

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC. and SCIELE )  
PHARMA CAYMAN LTD., )  
Plaintiffs, )  
v. ) Civil Action No. 07-00664 (GMS)  
MYLAN PHARMACEUTICALS, INC. and ) ORAL ARGUMENT REQUESTED  
MYLAN LABORATORIES, INC., )  
Defendants. )

**DECLARATION OF WILLIAM A. RAKOCZY, ESQ.**

I, William A. Rakoczy, declare as follows:

1. I am an attorney-at-law admitted to practice in the District of Columbia and in the State of Illinois, and am a partner in the firm of RAKOCZY MOLINO MAZZOCHI SIWIK LLP, counsel for Defendants Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc. (collectively "Mylan"). In such capacity, I am fully familiar with the facts contained herein.
2. I have submitted an application for leave to appear *pro hac vice* on behalf of Mylan in the above-captioned matter. This application is currently pending. I have previously been admitted *pro hac vice* on other matters before the Court.
3. I submit this Declaration to authenticate and provide to the Court certain documents, cited to and referenced in the accompanying Memorandum In Support Of Defendant Mylan's Rule 12(b)(1) Motion To Dismiss Plaintiff Sciele's Complaint For Lack Of Standing And Subject Matter Jurisdiction.
4. A true and accurate copy of U.S. Patent No. 4,892,741 (the '741 patent") is attached hereto as Exhibit A.

5. A true and accurate copy of a February 13, 2002 Press Release entitled "First Horizon Announces Agreement to Acquire the Antihypertensive Drug Sular – nisoldipine – From AstraZeneca," is attached hereto as Exhibit B.

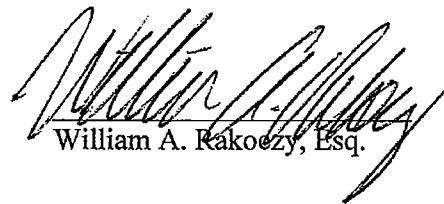
6. A true and accurate copy of the U.S. Patent and Trademark Office electronic assignment record reflecting the March 7, 2005 assignment of the '741 patent from Bayer Aktiengesellschaft to Bayer Healthcare AG, is attached hereto as Exhibit C.

7. A true and accurate copy of the December 12, 2001 Distributorship Agreement between Bayer AG and First Horizon Pharmaceutical Corporation (predecessor company to Sciele Pharma, Inc.), is attached hereto as Exhibit D.

8. A true and accurate copy of Sciele Pharma, Inc.'s/First Horizon Pharmaceutical Corporation's Form 10-K dated March 28, 2002, is attached hereto as Exhibit E.

I, William A. Rakoczy, hereby declare under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America that the foregoing Declaration is true and correct to the best of my knowledge.

Dated: December 18, 2007



William A. Rakoczy, Esq.

# EXHIBIT A

**United States Patent** [19]  
**Ohm et al.**

[11] **Patent Number:** **4,892,741**  
[45] **Date of Patent:** **Jan. 9, 1990**

[54] **PRESS COATED DHP TABLETS**

[75] **Inventors:** Andreas Ohm, Neuss; Helmut Luchtenberg, Niederkassel; Shinji Maegata, Oharanaka; Wolfgang Opitz, Overath, all of Fed. Rep. of Germany

[73] **Assignee:** Bayer Aktiengesellschaft, Leverkusen, Fed. Rep. of Germany

[21] **Appl. No.:** 204,056

[22] **Filed:** Jun. 8, 1988

[30] **Foreign Application Priority Data**

Jun. 24, 1987 [DE] Fed. Rep. of Germany 3720751

[51] **Int. Cl. 4** A61K 9/36

[52] **U.S. Cl.** 424/479; 424/474; 424/480; 424/482

[58] **Field of Search** 424/482, 480, 479, 494, 424/474

[56] **References Cited**

**U.S. PATENT DOCUMENTS**

3,184,386 5/1965 Stephenson 424/479 X  
3,558,768 1/1971 Klippel 424/480 X  
4,654,206 3/1987 Okuda et al. 424/480

4,765,990 8/1988 Sigimoto et al. 424/494  
4,803,081 2/1989 Falk et al. 424/480 X

**FOREIGN PATENT DOCUMENTS**

2331375 6/1977 France  
1144915 3/1969 United Kingdom  
2123291 2/1984 United Kingdom 424/480

**OTHER PUBLICATIONS**

104:174662y, Kimura et al., "Controlled-Release Pharmaceuticals Containing Nifedipine . . .", Chem. Ab. V. 104, May 1986, p. 391.

T. Wagner, "Die Praxis der Mantel-und Mehrschicht-tablette", Pharmazeutische Industrie, v. 24 (9/1962) pp. 417-422.

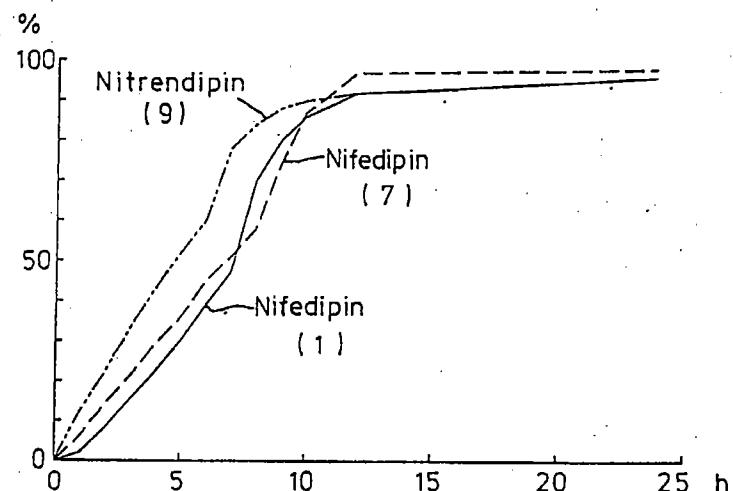
*Primary Examiner*—Thurman K. Page

*Attorney, Agent, or Firm*—Sprung Horn Kramer & Woods

[57] **ABSTRACT**

The invention relates to solid pharmaceutical preparations which have a long-lasting action and are for dihydropyridines in the form of a press coated tablet, and a process for their preparation.

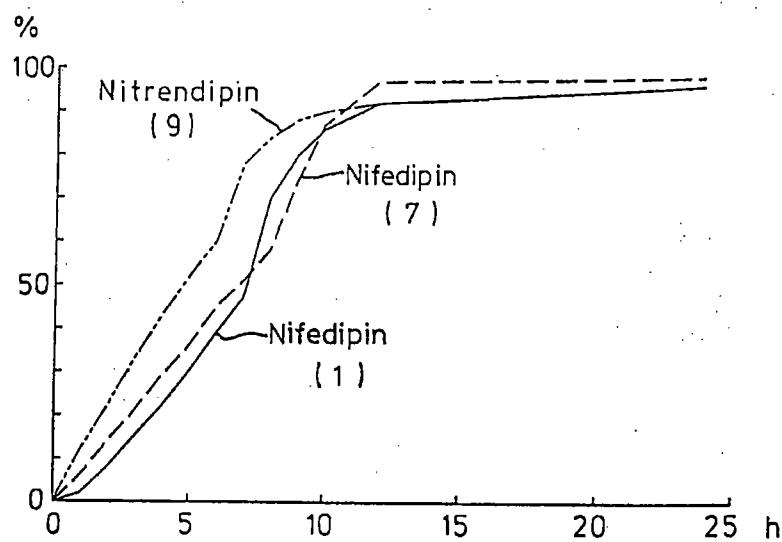
**12 Claims, 1 Drawing Sheet**



**U.S. Patent**

**Jan. 9, 1990**

**4,892,741**



**FIG. 1**

## PRESS COATED DHP TABLETS

Active compounds from the dihydropyridine class of substances and their use as cardiac and circulatory agents have already been disclosed (compare Brit. Pat. 1,173,862, Brit. pat. 1,358,951, US-Pat. 4,256,749, German Offenlegungsschrift 3,311,003 and U.S. Pat. No. 4,264,611). Difficulties frequently appear in the galenical preparation of these potent active compounds, in that the substances possess only a very low solubility, are frequently light-sensitive and their absorbability in biological systems frequently leads to problems. Numerous experiments have been undertaken to produce galenical preparations which improve the bioavailability of these potent active compounds. Thus, for example, some active compounds have been dissolved in specific organic solvent systems and filled into gelatine capsules in order to ensure a rapid and effective commencement of action (compare Brit. Pat. 1,362,627). The conversion of dihydropyridines such as nifedipine into co-precipitates or into "solid solutions" has also been attempted using water-soluble polymers, in order to improve the bioavailability (compare Brit. Pat. 1,579,818).

For the treatment of illnesses which must be treated over relatively long periods of time, such as, for example, hypertension, it is desirable to keep the frequency of administration of medicaments as low as possible. This is not only more agreeable for the patient, but also increases the safety of the treatment by diminishing the disadvantages of irregular administration and leads to a uniform active compound concentration/time profile in the body. The risk of under- or overdosing is thereby minimized at the same time.

Both for the physician and also for the patient, there is a demand, for example for the continuous therapy or circulatory diseases, to have available the highly active dihydropyridines in a form in which a once daily application suffices for treatment of the disease. Medicament preparations having delayed release of active compound (retard forms) have already been described for dihydropyridines. Thus, for example, the production of a slow-release preparation has been attempted by specific particle size distribution of the crystalline active compound or by a selected specific surface area of the crystals of the active compound (compare German Offenlegungsschrift 3,033,919). Furthermore, specific tablet preparations have been proposed which, according to the principle of the osmotic pump, release the active compound from the interior of a tablet which is provided with a semi-permeable coating layer through a given opening over a relatively long period of time and thus to achieve a retard effect (compare U.S. Pat. No. 3,916,899).

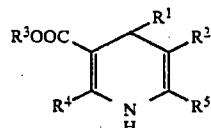
The previously known forms of preparation having retarded release of active compound, in particular those for dihydropyridines, exhibit a number of disadvantages. Their retard action is, for example, only limited to a few hours in some forms, so that the patient must, as a rule, administer them two or more times daily as before. After a few hours, the rate of release of the active compound decreases markedly, so that the blood level can also drop beneath the necessary efficacy limit.

In German Offenlegungsschrift 2,651,176, pellets having controlled release of active compound are described. The formulations described there differ fundamentally from the coated tablets according to the inven-

tion, since these pellets can only be obtained in complex processes by continuous application of many layers, whereas the tablet according to the invention is prepared by simple compression. An additional substantial difference is that the spherical pellets according to this Offenlegungsschrift even when they are produced in tablet dimensions, show a terminally decreasing release rate as opposed to the stepwise terminally increasing release rate of the coated tablets according to the invention. In the embodiment examples described there, only readily soluble active compounds are employed and all the examples describe the preparation of the pellet layers using lipophilic retarding agents. The use according to the invention of hydrophilic polymers, in particular hydroxypropyl-cellulose, cannot be carried out practically by the embodiment examples of this Offenlegungsschrift.

In the abovementioned osmotic system, local irritation of the tissue can occur in the stomach or gastrointestinal tract, depending on the capsule filling employed, owing to excessive concentration. Furthermore, a flattening of the release curve in the terminal region is also to be observed in the case of this osmotic retardation principle, which should ensure a linear course of release over a relatively long period of time. Due to the nature of the osmotic system, some of the active compound remains in the medicament form and is thus not available for the desired absorption. An additional disadvantage of this system is the delayed setting in of active compound release after administration, which in some cases only begins after about 2 hours. In addition, the production of this medicament form is very expensive, since organic solvents must be employed in the preparation process here and the coating layer of each tablet must be perforated separately with the aid of a laser beam.

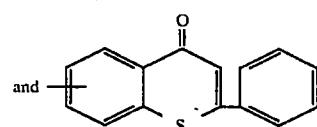
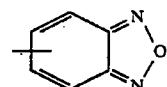
It has now been found that solid medicament preparations which have a long-lasting action in the form of a coated tablet and which contain a sparingly soluble dihydropyridine active compound of the general formula I



I

in which

R<sup>1</sup> represents a phenyl radical which is substituted by one or two identical or different substituents from the group comprising nitro, halogen and trifluoromethyl, or R represents a radical from the group comprising



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$R^2$  represents a nitro group or the radical  $COOR_6$ , in which

$R_6$  denotes alkyl having 1 to 10 C atoms which is optionally substituted by alkoxy having 1 to 4 C atoms or by one or more halogens, or in which

$R^2$ , together with  $R^5$ , represents the lactone group  $-CO-O-CH_2-$ ,

$R^3$  represents alkyl having 1 to 10 C atoms, which is optionally substituted by alkoxy having 1 to 4 C atoms or by one of more fluorine atoms and  $R^4$  and  $R^5$  are identical or different and in each case represent alkyl having 1 to 4 C atoms, which is optionally substituted by hydroxyl,

where the coated tablet

(a) consists of a core which contains at least one of the abovementioned dihydropyridines in rapid-release form and

(b) consists of a coating around the core, this coating containing at least one of the abovementioned dihydropyridines in slow-release form, show a surprisingly long-lasting efficacy.

Coated tablets may be preferably mentioned which contain 5% to 50%, preferably 10% to 40%, of the total dihydropyridine active compound in the core and which contain 50% to 95%, in particular 60% to 90%, of the total dihydropyridine active compound in the coating.

Particularly preferred active compounds which may be mentioned are nifedipine, nitrendipine, nimodipine and nisoldipine.

According to the type of active compound, the coated tablets according to the invention preferably contain 1 to 200 mg in total, in particular 10 to 150 mg, of at least one active compound from the dihydropyridine class.

The rapid-release core of the coated tablet preferably contains the active compound in amorphous form or in finely grounded or micronized crystalline form. When using crystalline active compound, the release rate is preferably influenced by the addition of auxiliaries with good water solubility and by alteration of the particle size distribution of the active compound.

Tablet cores having rapid release are preferably those cores which release 75% of the dihydropyridine active compound in one hour, preferably in 30 minutes, under the following conditions: 4 liters of 0,1N hydrochloric acid and 0,1-0,5% of weight of surfactant e.g. TWEEN 80 or sodiumlaurylsulphate; 37° C.; 100 Rpm; USP-Padme method.

If the rapid-release core contains amorphous dihydropyridine, the latter is preferably dissolved in an organic solvent together with water-soluble polymers such as polyvinylpyrrolidone, methylcellulose, hydroxypropyl-cellulose or hydroxypropylmethylcellulose. It is expedient here to employ 2 to 10 parts by weight, in particular 3 to 8 parts by weight, of the water-soluble polymers to 1 part by weight of dihydropyridine and to prepare suitable co-precipitates from this.

If the rapid-release core contains dihydropyridines in crystalline form, dihydropyridine crystals having a maximum mean particle size of about 25  $\mu$ m, in particular a maximum mean particle size of about 15  $\mu$ m, are preferably employed. The particle size is determined by the Cilas method (lit.: A. Buerkholz et al, Part. Charact. 1, 1984, 153-160, "Laser defraction spectrometers/experience in particle size analysis").

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When using crystalline dihydropyridine in the core, the addition of readily water-soluble auxiliaries such as, for example, lactose is expedient. Likewise, the release rate can be accelerated by the use of disintegrants, such as, for example, crosslinked polyvinylpyrrolidone (PVP), or surface-active substances, such as, for example, sodium lauryl sulphate.

The preparation of this rapid-release core takes place by customary methods (compare German Offenlegungsschrift 3,415,128 and German Offenlegungsschrift 3,142,853 or Brit. Pat. 1,579,818).

The granules for the coat of the tablet contain 10 to 99%, preferably 20 to 90%, of the total coating weight of hydrophilic gel-forming polymers.

Suitable hydrophilic gel-forming polymers are, for example, modified starch or cellulose-like substances such as, for example, methylcellulose, hydroxypropylmethyl-cellulose, hydroxypropylcellulose and sodium carboxymethyl-cellulose. Hydroxypropylcellulose (HPC) may be mentioned as being particularly preferred (compare: Hagers Handbuch der pharmazeutischen Praxis (Hager's Handbook of Pharmaceutical Practice), volume 7, part B, (1977) 130-141).

Various types of HPC can be used according to the invention, in each case differing in their viscosity, for example HPC-L (low viscosity of about 6-10 mPa.s), HPC-M (medium viscosity of about 150 mPa.s) and HPC-H (high viscosity of about 1000-4000 mPa.s). The release rate can be controlled through the different viscosity grades, the release rate increasing when lower viscosity grades are employed and slowing when using higher viscosity types.

In some cases, it is expedient to apply some of the active compound as the initial dose in the form of an outer layer of the coated tablet using the known techniques and auxiliaries.

Customary known galenical measures, such as, for example, the coating of the core with a gastric juice-resistant layer, the use of flavorings and aromas and lubricants and customary auxiliaries which are familiar to the galenical expert, can of course also be employed and used in the press coated tablets according to the invention.

It should be expressly pointed out that the coated tablet according to the invention differs from the previously known coated tablets due to the fact that the coating contains the active compound in slow-release form and the core contains the active compound in rapid-release form.

Multi-layer tablets based on casein matrices, which contain two or three layers which in each case can in turn contain active compounds (compare U.S. Pat. No. 3,184,386), have already been described in the prior art. The tablets described there contain a rapid-release preparation in the outer coating, the core primarily having the function of not allowing the surface of the outer active compound-containing layer relevant for the release to become too small. This patent specification contains no indication, however, that the core of the preparation contains a sparingly soluble active compound in rapid-release form. On the contrary, both the central coat and also the core are described in the examples as slow-release-forms of highly soluble active compounds.

Coated tablets which contain active compounds in slow-release form both in the core and in the coating are also described in U.S. Pat. No. 3,558,768. The release rates according to this US patent specification may be

different, but the specification refers only to slow-release forms.

Through the principle of the coated tablet according to the invention, the hitherto customary disadvantages of normal retard tablets and also of previously known multilayer or coated tablets or of preparation forms which depend upon the osmotic principle are avoided. In particular, the situation where the release rate of the active compound becomes smaller and smaller towards the end of the dissolution of the tablets and the plasma levels thus sink is avoided. The decreasing release rate of normal retard tablets due to a reduction in the volume of the tablet is more than compensated for by the rapid-release action of the core of the press coated tablet according to the invention. Complete release of the active compound is achieved at the same time, in contrast to osmotic systems.

The formulation according to the invention differs from all previously known retardation principles for solid medicament forms through the accelerated release rate in the terminal region.

Any reduced absorption of the administered medicament substance in deeper intestinal sections, for example limited by hindrance of diffusion, may thus be better equalized. Further advantages which may be mentioned are the rapid influx of the active compound after administration with the avoidance of a retardation phase and also the simple preparation technology. A further advantage of the inventive formulations is, that they are especially useful for those drugs, which show a higher resorption in the lower parts of the gastro intestinal tracts e.g. in the colon. This may lead to an increase of the bioavailability of those drugs.

Inventive composition can be manufactured by the following procedure:

(A) Core:

In accordance with usual techniques the active substance and the other ingredients are mixed and granulated by adding an aqueous solution of binders, e.g. in a planetary mixer or in a high speed mixer or by fluidized bed granulation. The granulate is dried, preferably in a fluidized bed dryer. The dried granulate is sieved and mixed with magnesiumstearate and afterwards pressed to tablets. Alternatively the manufacture of the core can be made by direct compression of the ingredients or by roller compaction plus compression. Optionally the core can be coated by usual methods, preferably in a coating pan or by other usual means.

Granules for the coat:

The granulate is produced preferably in a fluidized bed granulator by spraying an aqueous suspension containing the active substance and a binder on the solid ingredients, the obtained granules are dried, sieved and mixed with a lubricant, e.g. magnesiumstearate.

The production of the granules can also be made by other usual techniques.

Press coating:

The press coating of the core is carried out on usual press coaters (e.g. machines of the company Kilian or Manesty).

Optionally the press coated tablets can be film coated with usual laquers. In certain cases it may be recommendable to incorporate a small amount of the active substance into this film coating layer, the maximum amount of the active substance in the film coating layer

should be 20% of the total amount of the active substance.

With regard to the long existing requirement for medicament preparation forms having a long-lasting action, it is more than surprising that hitherto nobody has described or produced the coated tablets according to the invention having a rapid-release core which are simple to produce and very effective. Through the present invention, the patient is placed in the position of only having to take the medicament once daily, which in continuous therapy, in particular, represents a safer and more agreeable type of treatment.

The curves in FIG. 1 show for several examples according to the invention the principle of the coat of the tablet which is slowly released over several hours and the core which is released rapidly.

## ILLUSTRATIVE EMBODIMENTS

### Example 1

(A) Core

50 g of crystalline nifedipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 388 g of lactose and 150 g of corn starch, and the mixture is granulated in a paste of 10 g of starch and 140 g of hot water and then dried. The granules are sieved and mixed with 50 g of microcrystalline cellulose and 2 g of magnesium stearate. This mixture is compressed to 65 mg weight tablets having a diameter of 6 mm. The cores are coated for resistance to gastric juice using an organic solution of hydroxypropylmethylcellulose phthalate. The coated tablets weigh 72 mg.

(B) Granules for the coat

250 g of nifedipine are mixed with 400 g of lactose, 16 g of colloidal silica, 700 g of type M hydroxy-propylcellulose, 1747 g of type L hydroxypropylcellulose (HPC) and 320 g of citric acid, and the mixture is granulated in a fluidized bed granulator with a solution of 20 g of type L hydroxypropyl-cellulose. The dried and sieved granules are mixed with 27 g of magnesium stearate.

These granules and the cores described under (A) are pressed to 420 mg weight press coated tablets having a diameter of 10 mm in a press coater. The tablets are then coated using an aqueous dispersion of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red.

### Example 2

(A) Core

Preparation as in Example 1.

(B) Granules for the coat: 400 g of lactose are mixed with 17 g of colloidal silica, 2196 g of type L hydroxypropyl-cellulose, 250 g of type M hydroxypropylcellulose and 320 g of citric acid, and the mixture is granulated with an aqueous suspension of 250 g nifedipine and 20 g of type L hydroxypropyl-cellulose in a fluidized bed granulator. The dried granules are sieved and mixed with 27 g of magnesium stearate.

These granules and the cores described under (A) are pressed to 420 mg weight press coated tablets having a diameter of 10 mm in a press coater. The tablets are then coated using an aqueous dispersion of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red.

### Example 3

(A) Core

50 g of crystalline nifedipine (mean particle size 8  $\mu\text{m}$ ) are mixed with 291 g of lactose and 162.5 g of corn starch, and the mixture is granulated using a paste of 7.5 g of corn starch in 100 g of hot water. The granules are dried, sieved and then mixed with 1.5 g of magnesium stearate and 37.5 g of microcrystalline cellulose. This mixture is compressed to 55 mg weight cores having a diameter of 5.5 mm.

(B) Granules for the coat

400 g of lactose are mixed with 17 g of colloidal silica, 1105 g of type L HPC, 443 g of type M HPC and 202 g of citric acid, and the mixture is granulated using an aqueous suspension consisting of 250 g of nifedipine and 16 g of type L HPC. The granules are dried and sieved and mixed with 17 g of magnesium stearate.

Press coated tablets having a weight of 300 mg and a diameter of 9 mm are produced from these granules and the cores. The tablets are then coated as in Example 1.

Example 4

(A) Core

Preparation as in Example 3.

The cores are coated for resistance to gastric juice using an organic solution of hydroxypropylmethylcellulose phthalate. The coated tablets weigh 60 mg.

(B) Granules for the coat

250 g of nifedipine are mixed with 400 g of lactose, 17 g of colloidal silica, 1155 g of type L HPC, 343 g of type M HPC and 202 g of citric acid, and the mixture is granulated using an aqueous solution of 16 g of type L HPC. The granules are dried, sieved and mixed with 17 g of magnesium stearate.

Press Coated tablets having a weight of 300 mg and a diameter of 9 mm are prepared from these granules and the cores. The tablets are then coated as in Example 1.

Example 5

(A) Core

250 g of crosslinked polyvinylpyrrolidone and 197 g of microcrystalline cellulose are mixed and granulated using a solution of 30 g of nifedipine and 150 g of polyvinylpyrrolidone 25 in 350 g of acetone. The granules are dried and sieved and pressed with 3 g of magnesium stearate. This mixture is pressed to 65 mg weight tablets having a diameter of 6 mm. The cores are coated using an organic solution of hydroxypropylmethylcellulose phthalate. The coated cores weigh 72 mg.

(B) Granules for the coat

The granules are prepared analogously to Example 1. The additional processing is as in Example 1.

Example 6

(A) Core

Preparation as in Example 3.

(B) Granules for the coat

200 g of nifedipine are mixed with 350 g of lactose, 17 g of colloidal silica, 1105 g of type L HPC, 443 g of type M HPC and 202 g of citric acid, and the mixture is granulated using an aqueous solution of 16 g of type L HPC. The granules are dried and sieved and mixed with 12 g of magnesium stearate.

Press Coated tablets having a weight of 290 mg are pressed from these granules and the cores.

5 mg of nifedipine per tablet are coated onto these tablets from an aqueous dispersion containing hydroxypropylmethylcellulose and polyethylene glycol. These tablets are then covered with a light protecting coating analogously to Example 1.

Example 7

(A) Core

50 g of crystalline nifedipine (mean particle size 10  $\mu\text{m}$ ) are mixed with 600 g of lactose and 228 g of corn starch, and the mixture is granulated using a paste of 20 g of starch and 320 g of water and then dried. The granules are sieved and mixed with 2 g of magnesium stearate, and the mixture is pressed to 90 mg weight tablets having a diameter of 7 mm. The cores are coated using an organic solution of hydroxypropylmethylcellulose phthalate. The coated cores weigh 97 mg.

(B) Granules for the coat

250 g of nifedipine are mixed with 400 g of lactose and 16 g of colloidal silica, and the mixture is granulated using a solution of 16 g of type L hydroxypropylcellulose in water. The dried and sieved granules are mixed with 900 g of type M hydroxypropylcellulose, 2387 g of type L hydroxypropylcellulose, 400 g of citric acid and 61 g of magnesium stearate.

These granules and the cores described under (A) are pressed to 540 mg weight tablets having a diameter of 11 mm in a press coater. The tablets are then coated using an aqueous dispersion of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red.

Example 8

(A) Core

100 g of crystalline nifedipine (mean particle size 4  $\mu\text{m}$ ) are mixed with 241 g of lactose and 162.5 g of corn starch, and the mixture is granulated with a paste of 7.5 g of corn starch in 100 g of water. The dried granules are sieved and mixed with 1.5 g of magnesium stearate and 37.5 g of Avicel and this mixture is pressed to 55 mg weight tablets having a diameter of 5.5 mm.

(B) Granules for the coat

500 g of nifedipine are mixed with 335 g of lactose and 16 g of colloidal silica, and the mixture is granulated using a solution of 33 g of type L hydroxypropylcellulose in water. The dried granules are sieved and mixed with 443 g of type M hydroxypropylcellulose, 1105 g of type L hydroxypropylcellulose and 18 g of magnesium stearate.

These granules and the cores described under (A) are pressed to 300 mg weight tablets having a diameter of 9 mm in a press coater. The tablets are then coated using an aqueous dispersion of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red.

Examples 9 and 10 were prepared in an analogous manner.

Example 9

Core:

nitrendipine mean particle size 6 $\mu\text{m}$	5.0 mg
corn starch	27.8 mg
microcrystalline cellulose	20.0 mg
lactose	21.49 mg

are mixed and then granulated with:

polyvinylpyrrolidone 25	5.0 mg
sodium lauryl sulphate	0.5 mg
FD + C blue lake No. 2	0.01 mg

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in aqueous suspension by means of customary granulation processes

10

-continued

after drying, magnesium stearate 0.2 mg

is admixed. The mixture is pressed to cores in a tablet press: weight: 80 mg, size:  $\phi$ 6 mm

Granules for the coat:

type L hydroxypropylcellulose	210.0 mg
type M hydroxypropylcellulose	82.0 mg
citric acid	146.0 mg

are mixed and granulated with an aqueous suspension of

nitrendipine (mean particle size 5 $\mu$ m)	25.0 mg
hydroxypropylcellulose type L	2.0 mg
after drying admixing of magnesium stearate	5.0 mg

Press Coated tablets are prepared with the aid of a press coater Total weight: 550 mg Size:  $\phi$ 10 mm

#### Example 10

Core:

nitrendipine mean particle size 5 $\mu$ m	5.0 mg
microcrystalline cellulose	17.5 mg
lactose	6.4 mg
corn starch	7.5 mg
mixing and granulation with	
polyvinylpyrrolidone 25	3.0 mg
sodium lauryl sulphate	0.5 mg

in aqueous solution by means of customary granulation processes after drying,

magnesium stearate	0.1 mg
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is admixed and the mixture is pressed to cores in a tablet press: weight: 40 mg, size:  $\phi$ 5.5 mm

Granules for the coat:

micronized nitrendipine	25.0 mg
type L hydroxypropylcellulose	221.0 mg

are mixed and granulated (if desired a part of the hydroxypropylcellulose can be removed for processing in the granulation liquid)

admixing of magnesium stearate	7.0 mg
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Press Coated tablets are prepared with the aid of a press coater. Total weight: 293 mg Size: 9 mm

#### Example 11

Core:

nitrendipine (mean particle size 10 $\mu$ m)	2.5 mg
corn starch	23.0 mg
microcrystalline cellulose	20.0 mg
lactose	21.5 mg

10

-continued

Plasdone XL	7.3 mg
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5 are granulated using an aqueous solution of:

polyvinylpyrrolidone 25	5 mg
sodium lauryl sulphate	0.5 mg

10 after drying,

magnesium stearate	0.2 mg
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15 is admixed and the mixture pressed to cores in a tablet press. Weight: 80 mg, size: 6 mm

Granules for the coat:

micronized nisoldipine	12.5 mg
type L hydroxypropylcellulose	212 mg
type M hydroxypropylcellulose	82 mg
lactose	158.5 mg

20 are mixed and granulated with water admixing of

magnesium stearate	12 mg
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25 Press Coated tablets are prepared with the aid of a press coater Total weight: 557 mg Size: 10 mm

#### Example 12

(A) Core

The preparation is as in Example 8, 200 g of nimodipine and 141 g of lactose now being employed instead of 100 g of nifedipine and 241 g of lactose.

(B) Granules for the coat

Preparation by analogy with Example 8, 600 g of nimodipine and 235 g of lactose now being employed instead of 500 g of nifedipine and 335 g of lactose.

The aqueous coating is likewise analogous to Example 8, but without the use of red iron oxide.

45 Example 13

(A) Core

The preparation is analogous to Example 8, 50 g of nifedipine, 150 g of nisoldipine and 141 g of lactose now being employed instead of 100 g of nifedipine and 241 g of lactose.

(B) Granules for the coat

The preparation is analogous to Example 8, 200 g of nifedipine and nisoldipine now being employed instead of 500 g of nifedipine.

55 At the same time, 518 g of HPC-M and 1030 l g of HPC-L are now used instead of 443 g of HPC-M and 1105 g of HPC-L.

60 Example 14

Core:

nitrendipine of mean particle size 5 $\mu$ m	8.0 mg
microcrystalline cellulose	12.0 mg
lactose	4.0 mg
Plasdone XL	15.0 mg

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mixing and granulation with

polyvinylpyrrolidone 25	2.0 mg
sodium lauryl sulphate	0.8 mg

in aqueous solution by means of customary granulation processes after drying,

magnesium stearate	0.2 mg
--------------------	--------

is admixed and the mixture is pressed to cores in a tablet press: weight: 42 mg, size: 5 mm

Granules for the coat:

micronized nitrendipine	32.0 mg
type L hydroxypropylcellulose	77.0 mg
type M hydroxypropylcellulose	77.0 mg
lactose	92.5 mg

are mixed and granulated (if desired a part of the hydroxypropylcellulose can be removed for processing in the granulation liquid)

admixing of magnesium stearate	1.5 mg
--------------------------------	--------

Press Coated tablets are prepared with the aid of a press coater. Total weight: 322.0 mg; size: 9 mm

## Example 15

## A. Core:

50 g Nifedipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 170 g lactose and 173,5 g corn starch. This mixture is granulated with an aqueous paste of 5 g corn starch. After drying and sieving 1,5 g magnesium stearate, 50 g plasdone XL and 50 g Avicel are added. The granules are compressed to tablets with a size of 5 mm and a weight of 50 mg.

## B. granules for the coat

1101 g hydroxypropylcellulose type L, 755 g hydroxypropylcellulose type M, 341 g lactose and 16 g of colloidal silica are mixed. This mixture is granulated using an aqueous suspension of 250 g nifedipine and 20 g HPC type L. The granules are dried and sieved and mixed with 17 g of magnesium stearate. Press coated tablets having a weight of 300 mg and a diameter of 9 mm are pressed from these granules and the cores.

## C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red in order to give light protection.

## Example 16

## A. Core

100 g nifedipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 160 g lactose, 148,8 corn starch. This mixture is granulated with an aqueous paste of 5 g corn starch. After drying and sieving 1,3 g magnesium stearate, 50 g plasdone XL and 34,9 g Avicel are added. The granules are compressed to tablets with a size of 5 mm and a weight of 50 mg.

## B. granules for the coat

1010 g hydroxypropylcellulose type L, 628 g hydroxypropylcellulose type M, 289 g lactose and 16 g of colloidal silica are mixed. This mixture is granulated

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using an aqueous suspension of 500 g nifedipine and 40 g HPC type L. The granules are dried and sieved and mixed with 17 g of magnesium stearate. Press coated tablets having a weight of 300 mg and a diameter of 9 mm are pressed from these granules and the cores.

## C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red in order to give light protection.

## Example 17

## A. Core

150 g nifedipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 130 g lactose, 124 g corn starch. This mixture is granulated with an aqueous paste of 5 g corn starch. After drying and sieving 1 g magnesium stearate, 50 g plasdone XL and 40 g Avicel are added. The granules are compressed to tablets with a size of 5 mm and a weight of 50 mg.

## B. granules for the coat

780 g hydroxypropylcellulose type L, 588 g hydroxypropylcellulose type M, 289 g lactose and 16 g of colloidal silica are mixed. This mixture is granulated using an aqueous suspension of 750 g nifedipine and 60 g HPC type L. The granules are dried and sieved and mixed with 17 g of magnesium stearate. Press coated tablets having a weight of 300 mg and a diameter of 9 mm are pressed from these granules and the cores.

## C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red in order to give light protection.

## Example 18

## A. Core

40 8 g nitrendipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 4 g lactose, 15 g crosslinked PVPP and 12,3 g microcrystalline cellulose. This mixture is granulated with an aqueous solution of 1,8 g PVP and 0,8 g sodium laurylsulfate. After drying and sieving 0,1 g magnesium stearate are added. The granules are compressed to tablets with a size of 5 mm and a weight of 42 mg.

## B. granules for the coat

50 104,5 g hydroxypropylcellulose type L, 40 g hydroxypropylcellulose type M and 88,5 g lactose are mixed. This mixture is granulated using an aqueous suspension of 32 g nitrendipine and 1,5 g HPC type L. The granules are dried and sieved and mixed with 1,5 g of magnesium stearate. Press coated tablets having a weight of 310 mg and a diameter of 9 mm are pressed from these granules and the cores.

## C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylmethylcellulose, polyethylene glycol and titanium dioxide.

## Example 19

## A. Core

65 20 g nitrendipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 15 g crosslinked PVP and 7,2 g microcrystalline cellulose. This mixture is granulated with an aqueous solution of 1,8 g PVP and 0,9 g sodium lauryl sulfate. After drying and sieving 0,1 g magnesium stearate are

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added. The granules are compressed to tablets with a size of 5 mm and a weight of 45 mg.

B. granule for the coat

144,5 g hydroxypropylcellulose type L and 97,5 g lactose are mixed. This mixture is granulated using an aqueous suspension of 20 g nifedipine and 1,5 g HPC type L. The granules are dried and sieved and mixed with 1,5 g of magnesium stearate. Press coated tablets having a weight of 310 mg and a diameter of 9 mm are pressed from these granules and the cores.

C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylmethylcellulose, polyethylene glycol and titanium dioxide.

Example 20

A. Core

4 g nifedipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 8 g lactose, 15 g crosslinked PVPP and 12,3 g microcrystalline cellulose. This mixture is granulated with an aqueous solution of 1,8 g PVP and 0,8 g sodium laurylsulfate. After drying and sieving 0,1 g magnesium stearate are added. The granules are compressed to tablets with a size of 5 mm and a weight of 42 mg.

B. granule for the coat

46,5 g hydroxypropylcellulose type L, 100 g hydroxypropylcellulose type M and 103 g lactose are mixed. This mixture is granulated using an aqueous suspension of 16 g nifedipine and 1,5 g HPC type L. The granules are dried and sieved and mixed with 1 g of magnesium stearate. Press coated tablets having a weight of 310 mg and a diameter of 9 mm are pressed from these granules and the cores.

C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red in order to give light protection.

Example 21

A. Core

4 g nifedipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 8 g lactose, 15 g crosslinked PVPP and 12,3 g microcrystalline cellulose. This mixture is granulated with an aqueous solution of 1,8 g PVP and 0,8 g sodium laurylsulfate. After drying and sieving 0,1 g magnesium stearate are added. The granules are compressed to tablets with a size of 5 mm and a weight of 42 mg.

B. granule for the coat

92,5 g hydroxypropylcellulose type L, 54 g hydroxypropylcellulose type M and 103 g lactose are mixed. This mixture is granulated using an aqueous suspension of 16 g nifedipine and 1,5 g HPC type L. The granules are dried and sieved and mixed with 1 g of magnesium stearate. Press coated tablets having a weight of 310 mg and a diameter of 9 mm are pressed from these granules and the cores.

C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylcellulose, polyethylene glycol, titanium dioxide and iron oxide red in order to give light protection.

Example 22

A. Core

4 g nifedipine (mean particle size 5  $\mu\text{m}$ ) are mixed with 8 g lactose, 15 g crosslinked PVP and 12,3 g microcrystalline cellulose. This mixture is granulated with an

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aqueous solution of 1,8 g PVP and 0,8 g sodium laurylsulfate. After drying and sieving 0,1 g magnesium stearate are added. The granules are compressed to tablets with a size of 5 mm and a weight of 42 mg.

B. granule for the coat

175 g hydroxypropylcellulose type M and 74,5 g lactose are mixed. This mixture is granulated using an aqueous suspension of 16 g nifedipine and 1,5 g HPC type L. The granules are dried and sieved and mixed with 1 g of magnesium stearate. Press coated tablets having a weight of 310 mg and a diameter of 9 mm are pressed from these granules and the cores.

C. Coating

The tablets are then coated with an aqueous suspension of hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide and iron oxide red in order to give light protection.

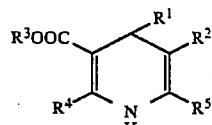
It will be understood that the specification and examples are illustrative but not limitative of the present invention and that other embodiments within the spirit and scope of the invention will suggest themselves to those skilled in the art.

We claim:

1. A solid medicament preparation having a long-lasting action in the form of a press coated tablet which contains a sparingly soluble dihydropyridine, the press coated tablet comprising

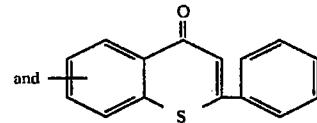
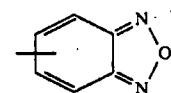
- (a) a core which contains a dihydropyridine in rapid-release form, and
- (b) a coat around the core, the coat containing a dihydropyridine in slow-release form.

2. A press coated tablet according to claim 1, wherein the dihydropyridine is of the formula



in which

R<sup>1</sup> represents a phenyl radical which is substituted by one or two identical or different substituents from the group comprising nitro, halogen and trifluoromethyl, or represents a radical from the group comprising



R<sup>2</sup> represents a nitro group or the radical COOR<sub>6</sub>, in which

R<sub>6</sub> denotes alkyl having 1 to 10 C atoms which is optionally substituted by alkoxy having 1 to 4 C atoms or by one or more halogens, or in which

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$R^2$ , together with  $R^5$ , represents the lactone group  $-\text{CO}-\text{O}-\text{CH}_2$ ,  $R^3$  represents alkyl having 1 to 10 C atoms, which is optionally substituted by alkoxy having 1 to 4 C atoms or by one or more fluorine atoms and  $R^4$  and  $R^5$  are identical or different and in each case represent alkyl having 1 to 4 C atoms, which is optionally substituted by hydroxyl.

3. A press coated tablet according to claim 1, containing about 5 to 50% of the total dihydropyridine in the core and about 95 to 50% of the total dihydropyridine in the coat.

4. A press coated tablet according to claim 1, containing about 10 to 40% of the total dihydropyridine in the core and about 90 to 60% of the total dihydropyridine in the coat.

5. A press coated tablet according to claim 1, wherein the core contains the dihydropyridine in amorphous form or in crystalline form having a maximum mean particle size of 25  $\mu\text{m}$ .

6. A press coated tablet according to claim 1, wherein about 10 to 99% of the total coat weight is a hydrophilic gel-forming polymer.

7. A press coated tablet according to claim 6, wherein the coat contains methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose and/or sodium carboxymethylcellulose as the hydrophilic gel-forming polymer.

8. A press coated tablet according to claim 7, wherein the coat contains hydroxypropylcellulose as the hydrophilic gel-forming polymer.

9. A press coated tablet according to claim 1, wherein the dihydropyridine comprises at least one compound

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selected from the group consisting of nifedipine, nifendipine, nimodipine and nisoldipine.

10. A press coated tablet according to claim 1, wherein the core contains the dihydropyridine in crystalline form and further contains at least one of a readily water-soluble auxiliary, disintegrant and wetting agent.

11. A press coated tablet according to claim 1, wherein the coating is itself coated with a layer of dihydropyridine in rapid-release form.

12. A process for manufacturing solid medicament preparations having a long lasting action containing a sparingly soluble dihydropyridine in form of a press coated tablet comprising:

- (a) a core which contains a dihydropyridine in rapid-release form, and
- (b) a coat around the core, the coat containing a dihydropyridine in slow-release form, the core having been produced by mixing the active substance and a filler, granulating this mixture by adding an aqueous solution of binder, drying and sieving the granulate, adding a lubricant and pressing to form the core, or forming the core by direct compression or by roller compaction plus compression, producing the granule for the coat by spraying an aqueous suspension containing the active substance and a binder on the solid ingredients, drying and sieving, mixing with a lubricant, press coating the granules for the coat upon the core, and optionally film coating the obtained press coated tablet with lacquers which optionally contain a small amount of the active substance up to a maximum of 20% of the total amount of the active substance in the whole composition.

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## **EXHIBIT B**



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## First Horizon Announces Agreement to Acquire the Antihypertensive Drug Sular - nisoldipine - From AstraZeneca.

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Business Editors/Health &amp; Medical Writers

ROSWELL, Ga.-(BUSINESS WIRE)-Feb. 13, 2002

First Horizon Pharmaceutical(TM) Corporation (Nasdaq:FHRX), a specialty pharmaceutical company, announced today that it has entered into a definitive agreement to acquire certain U.S. rights relating to the antihypertensive prescription medication Sular(R)(nisoldipine) from AstraZeneca UK Limited ("AstraZeneca"). The Company has also entered into a long-term manufacturing, supply and distribution agreement with Sular's current manufacturer Bayer AG. Sular is a patented, once-a-day treatment for high blood pressure (hypertension), and competes in the approximately \$16 billion antihypertensives market. Sular had U.S. net sales of approximately \$46 million in 2001. The purchase price for the transaction is \$185 million plus the assumption of certain liabilities. In addition, the Company may pay up to \$30 million in additional purchase price after closing, based on the achievement of certain performance milestones. The Company anticipates that it will complete the transaction in the first quarter of 2002, subject to approval under the Hart-Scott-Rodino Act and the satisfaction of certain other customary closing conditions.

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"This represents the most significant product acquisition to date for First Horizon," said Mahendra G. Shah, Ph.D., Chairman, President and CEO of First Horizon Pharmaceutical. "We are excited about this opportunity to acquire the rights to market a product of Sular's therapeutic characteristics and market potential. This product will fit nicely within our cardiovascular franchise because the physicians who prescribe our Nitrolingual(R) Pumpspray product for acute angina comprise a large part of the target audience for Sular. In addition, many patients who suffer from acute angina also suffer from hypertension. We believe that Sular offers advantages based upon its proven efficacy and safety, its demonstrated ability to provide 24-hour blood pressure reduction, and its value on a cost per day basis. We believe we can increase sales of this product through active promotion to targeted physicians within the antihypertensive market," continued Dr. Shah.

"We plan to launch Sular in the second quarter of 2002. We believe we can increase Sular's sales by targeting selected cardiologists and high-prescribing primary care physicians. We currently have strong coverage of cardiologists through our promotion of Nitrolingual Pumpspray. We plan to achieve increased reach to primary care physicians by adding approximately 50 sales representatives and managers to our sales force this year and by partnering with an external sales organization experienced in promoting products to these specialties," explained Bala Venkataraman, Executive Vice President, COO and CFO.

In order to finance the acquisition, the Company intends to use its available cash and has received a commitment for a six-month \$152 million senior secured credit facility, arranged through Deutsche Banc Alex. Brown Inc., which also acted as financial advisor to First Horizon in connection with this transaction.

Dr. Shah stated, "The Company would like to have a strong cash position and strong balance sheet to continue to execute our long-range plans and is therefore evaluating our options to raise capital as market conditions allow."

"We expect that the Sular acquisition will be neutral to earnings in 2002 and accretive to earnings beginning in 2003. We expect net sales for 2002 to be between \$127 million and \$132 million. Assumptions underlying this guidance include credit facility borrowings on approximately the same terms as the interim financing associated with the acquisition remaining outstanding and the incurrence of certain costs associated with our launch of Sular," continued Mr. Venkataraman.

Sular was developed and patented by Bayer AG and was approved by the Food and Drug Administration in 1995. In 1996, Bayer AG granted to Zeneca Limited, a predecessor entity to AstraZeneca, the exclusive right to market, distribute and sell products containing nisoldipine in the U.S. As part of this transaction, Bayer will grant to First Horizon an exclusive ten-year license to its patents and other intellectual property for the sale of Sular in the United States. Bayer has also agreed to supply First Horizon with Sular during the term of this license. Sular is protected by Bayer's formulation patent that expires in June 2008.

"The Sular acquisition is an exciting step for First Horizon and enables us to build upon our cardiovascular franchise. We are creating a focused company by building our franchises in cardiology, obstetrics and

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## First Horizon Announces Agreement to Acquire the Antihypertensive Drug Sular - nisold... Page 2 of 4

gynecology, pediatrics and gastroenterology. In addition to this new product within our cardiovascular franchise, we've added the Prenate(TM) line to our obstetrics and gynecology franchise and Furadantin(R) and Tanafed(TM) DM to our pediatric franchise in recent months," Dr. Shah said.

Mr. Venkataraman added, "We look forward to a successful launch of Sular while continuing to increase sales of our other key products. We will also continue to focus on acquiring attractive products to add to our four therapeutic franchises, while managing our product lifecycles through prudent investments in developing line extensions."

First Horizon Pharmaceutical Corporation will host a conference call on Wednesday February 13, 2002 at 9:00 a.m. Eastern time. You are welcome to listen to the webcast of this call by visiting the Company's website at [www.firsthorizonpharm.com](http://www.firsthorizonpharm.com) and entering the Investor Relations page. If you wish to dial into the conference call the numbers are 800-530-9010 for domestic callers and 212-346-0300 for international callers. A replay of this conference call will be made available for one week by dialing 800-633-8284 for domestic callers and 858-812-6440 for international. The reservation number for both domestic and international callers is 20341580.

Nisoldipine, the active ingredient in Sular, belongs to a group of medicines called **calcium-channel blockers**. Calcium-channel blockers prevent calcium from entering certain types of muscle cells. Because the muscle cells need calcium to contract, calcium-channel blockers prevent the cells from contracting and cause them to relax. Nisoldipine selectively relaxes the muscles of small arteries causing them to dilate but has little or no effect on muscles or the veins of the heart.

Sular is a long-acting, once-a-day drug that may be used alone or in combination with other blood pressure medications. In rare cases, some patients, particularly those with severe obstructive coronary artery disease, have developed increased frequency, duration and/or severity of angina, or acute myocardial infarction on starting calcium-channel blocker therapy or at the time of dosage increase. Because nisoldipine, like other vasodilators, decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of Sular is recommended. Safety of Sular in patients with heart failure has not been established. Sular should be administered cautiously in patients with severe hepatic dysfunction. Sular should not be taken with grapefruit juice or in conjunction with a high fat meal as increased bioavailability may result. The most common adverse events, reported in U.S. placebo-controlled trials, were, peripheral edema, headache and dizziness. See package insert for full prescribing information.

First Horizon Pharmaceutical Corporation is a specialty pharmaceutical company that markets and sells brand name prescription products in four therapeutic franchises to high-prescribing primary care and selected specialty physicians through its nationwide sales and marketing force. The Company focuses on the treatment of chronic conditions, including cardiovascular diseases, obstetrical and gynecological, pediatric and gastroenterological conditions and disorders.

#### Safe Harbor

This press release contains statements which constitute forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements include, without limitation, statements concerning (1) increasing sales of Sular, (2) increasing the sales force reach for Sular, (3) increasing the size of our sales force, (4) partnering with an external sales force, (5) plans to raise capital, (6) the effect of the Sular acquisition to our earnings in 2002 and thereafter, (7) forecasted net sales for 2002, and (8) increased sales of our other key products. Such statements are subject to certain factors, risks and uncertainties that may cause actual results, events and performance to differ materially from those referred to in such statements. In evaluating all forward-looking statements, you should specifically consider various factors that may cause actual results to vary from those contained in the forward-looking statements.

Risks related to our proposed acquisition of Sular include:

- There is no assurance that the conditions to our acquisition of Sular will be satisfied, and we may not acquire Sular,
- If we acquire Sular, our operating results will be substantially dependent upon the result of operations of Sular so that any factor adversely affecting Sular could have a material adverse effect on our sales and profits,
- There is no assurance that we can raise capital on acceptable terms to repay or refinance our six-month \$152 million senior secured credit facility which we expect to enter into in connection with the acquisition of Sular,
- Due to the size of the Sular acquisition and other recently completed acquisitions, we may incur unexpected costs in integrating Sular and other recently acquired products into our operations,
- Our acquisition of Sular will require adjustments to our sales force which we may not be able to complete successfully or sufficiently rapidly to achieve targeted sales of Sular,
- The potential growth rate for Sular may be limited by slower growth for the class of drugs to which Sular belongs and unfavorable clinical studies about such class of drugs,
- The level of debt we incur to acquire Sular could reduce our growth and profitability, and
- Strong competition exists in the sale of drugs that treat hypertension which could adversely affect expected growth of Sular sales or increase our costs to sell Sular.

Risks affecting forward-looking statements may also include:

- The Company may not be able to identify a manufacturer to supply Furadantin after May 2003,
- Patent rights do not protect Furadantin from competition,

-- Prior to the Prenate(TM) acquisition, the Company did not have experience marketing and selling prenatal vitamins, which may adversely impact the Company's launch of Prenate GT and the Company's ability to maintain sales of Prenate Advance,

- Patent rights do not protect the Prenate products from competition, except for the gel-coating on Prenate GT, and
- The regulatory status of prenatal vitamins may make Prenate products subject to increased competition.

Other risks affecting forward-looking statements include, without limitation, those identified in the Company's registration statement on Form S-1 previously filed with the Securities and Exchange Commission in the "Risk Factors" section under the following headings: "We currently depend on four key products for a large portion of our sales, and substantial declines in any of them would result in our being unprofitable", "There is no assurance of continued commercial acceptance of our products", "Our growth will suffer if we do not acquire rights to new products and integrate them successfully", "We may encounter problems in the manufacture of our products that could limit our ability to sell our products", "We face competition from generic products that could lower prices and unit sales", "Strong competition exists for our products, and competitors have introduced new products and therapies that could make our products obsolete", "A small number of customers account for a large portion of our sales and the loss of any of them, or changes in their purchasing patterns, could result in our inability to successfully sell our products", "If our products under development fail in clinical studies or if we fail or encounter difficulties in obtaining regulatory approval for new products or new uses of existing products, we will have expended significant resources for no return", "Our acquisition of Cognex creates additional risks", "We or third parties may violate government regulations and we may incur significant expenses to comply with such regulations", "If third-party payors do not adequately reimburse patients for our products, doctors may not prescribe them", "Product liability claims and product recalls could limit our ability to sell products", "We expect to require additional funding, and if we cannot obtain it, our sales, profits, acquisitions and development projects could suffer", "If we do not secure or enforce our patents or other intellectual property rights, we could encounter increased competition that could adversely affect our operating results", "Our products could infringe the intellectual property rights of third parties, which could require us to pay license fees or defend litigation that could be expensive or prevent us from selling products", "The regulatory status of some of our products makes these products subject to increased competition and other risks", "We face risks under one of our development agreements because the other party to the agreement is a related party", and "Pohl-Boskamp can terminate our rights to Nitrolingual". We do not undertake to update our forward-looking statements to reflect future events or circumstances.

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# EXHIBIT C



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Inventors: ANDREAS OHM, HELMUT LUCHTENBERG, SHINJI MAEGATA, WOLFGANG OPITZ

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Assignors: OHM, ANDREAS

Exec Dt: 05/24/1988

LUCHTENBERG, HELMUT

Exec Dt: 05/24/1988

MAEGATA, SHINJI

Exec Dt: 05/24/1988

OPITZ, WOLFGANG

Exec Dt: 05/24/1988

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Exec Dt: 03/07/2005

Assignee: [BAYER HEALTHCARE AG](#)

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Web interface last modified: April 20, 2007 v.2.0.1[HOME](#) | [INDEX](#) | [SEARCH](#) | [eBUSINESS](#) | [CONTACT US](#) | [PRIVACY STATEMENT](#)

# **EXHIBIT D**

EXHIBIT 10.34

CONFIDENTIAL TREATMENT REQUESTED  
Confidential Portions Of This Agreement  
Which Have Been Redacted Are Marked  
With Brackets ("[\*\*\*]"). The Omitted Material  
Has Been Filed Separately With The Securities  
And Exchange Commission.

DISTRIBUTORSHIP AGREEMENT

This Agreement is entered into and effective as of December 12, 2001 by and between Bayer AG, having its principal place of business at D-51368 Leverkusen, Federal Republic of Germany (hereinafter: "BAYER").

And

First Horizon Pharmaceutical Corporation having its principal place of business at 660 Hembree Parkway, Suite 106, Roswell, GA 30076, USA (hereinafter: "FIRST HORIZON").

WHEREAS, BAYER and Zeneca Limited, UK had concluded on a Distributorship Agreement on different strengths of a drug containing the active ingredient Nisoldipine (INN) marketed under BAYER's trademark Sular(R) in the United States of America;

WHEREAS, AstraZeneca Limited, UK, the legal successor of Zeneca Limited - hereinafter referred to as AZ - has decided, and - subject to certain conditions - BAYER has agreed thereto, to divest its business concerning the PRODUCTS to FIRST HORIZON; and

WHEREAS, the cooperation of the parties under this Distributorship Agreement ("AGREEMENT") is established with the intent of governing the exclusive marketing, distribution, use and sales of Nisoldipine (INN) coat-core tablets in the United States of America by FIRST HORIZON.

Now, therefore, the parties hereto agree as follows:

ARTICLE 1  
DEFINITIONS

Whenever used in this AGREEMENT the following words, when written in capitals, shall have the following meaning:

1.1 ACT shall mean the Federal Food Drug and Cosmetics Act of the United States of America, United States Code Title 21, Chapter I, as amended.

1.2 AE(s) (adverse event) shall mean any untoward medical occurrence in a patient or clinical investigation subject to whom a pharmaceutical product has been administered and which does not necessarily have to have a causal relationship with this treatment. AE can therefore be any

unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporarily associated with the use of a medicinal product, whether or not considered related to the medicinal product. [ICH; Guideline on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting March1 , 1995; Federal Register Vol. 60, No. 40, p. 11285; CPMP: Note for Guidance - "Clinical Safety Data Management) - Definitions and Standards for Expedited Reporting 111/3375/93 - Final.]

1.3 AFFILIATE shall mean any business entity which directly or indirectly controls, is controlled by, or is under common control with either PARTY to this Agreement. A business entity shall be deemed to "control" another business if it owns, directly or indirectly, in excess of fifty percent of the outstanding voting securities or capital stock of such business entity or other comparable equity or owner ship interest.

1.4 APPOINTMENT means BAYER'S appointment of FIRST HORIZON set forth in Section 2.1.

1.5 cGMP means United States of America current Good Manufacturing Practices as established from time to time by the FDA.

1.6 COMMERCIAL INFORMATION shall mean information relating to sales forecasts, PRODUCTS orders, actual NET SALES, NET SALES payments (as defined in Article 10.6, below), sample usage and similar information relating to sales and marketing of FINISHED PRODUCTS as may be exchanged pursuant to this AGREEMENT.

1.7 COMMERCIALLY REASONABLE EFFORTS shall mean efforts and resources normally used by a Party for a compound or product owned by it or to which it has rights, which is of similar market potential at a similar stage in its product life, taking into account the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, and other relevant factors.

1.8 DATE OF AGREEMENT shall mean the date first written above.

1.9 EFFECTIVE DATE means the date upon which the following conditions have been satisfied: (i) First Horizon (or an AFFILIATE thereof) consummates its acquisition of the assets of AZ relating to the PRODUCT and (ii) the respective GOVERNMENTAL AUTHORITIES of the TERRITORY, including the Federal Trade Commission and the FDA, have approved, to the extent required, the transactions contemplated hereby. The PARTIES agree to provide copies of these approvals to each other prior to the EFFECTIVE DATE and to inform AZ accordingly.

1.10 EURO shall mean the Euro, the official currency of the European Union.

1.11 FDA means the United States Food & Drug Administration.

1.12 FINISHED PRODUCTS shall mean the finished pharmaceutical preparations for human use in cardiovascular indications containing ready for sale PRODUCTS, as hereinafter defined and including samples thereof.

1.13 GOVERNMENTAL AUTHORITY shall mean (i) any domestic or foreign national, federal, provincial, state, municipal or other government or body, (ii) any international or multilateral body, (iii) any subdivision, ministry, department, secretariat, bureau, agency, commission, board, instrumentality or authority of any of the foregoing governments or bodies, (iv) any quasi-governmental or private body exercising any regulatory, expropriation or taxing authority under or for the account of any of the foregoing governments or bodies,

or (v) any domestic, foreign, international, multilateral, or multinational judicial, quasi-judicial, arbitration or administrative court, grand jury, tribunal, commission, board or panel.

1.14 INN shall mean International Non-Proprietary Name.

1.15 LAWS shall mean (i) all constitutions, treaties, laws, statutes, codes, ordinances, orders, decrees, rules, regulations, and municipal by-laws, whether domestic, foreign or international; (ii) all judgments, orders,

writs, injunctions, decisions, rulings, decrees, and awards of any GOVERNMENTAL AUTHORITY; and (iii) all policies, practices and guidelines of any GOVERNMENTAL AUTHORITY; in each case binding on or affecting the PARTY referred to in the context in which such word is used; and LAW shall mean any one of them.

1.16 NDA shall mean the New Drug Application filed with the FDA for FINISHED PRODUCTS, as defined in the ACT and the REGULATIONS.

1.17 NET SALES shall mean the gross sales of the FINISHED PRODUCTS in the TERRITORY by FIRST HORIZON, to unrelated third parties, including but not limited to, pharmaceutical wholesalers, pharmacies, hospitals, hospital GPOs, Health Maintenance Organizations, Preferred Provider Organization, Individual Practice Associations, Pharmacy Services Administrative Organizations, Pharmacy Benefit Companies, or dispensing physicians, less, as properly evidenced, any of the following charges or expenses that are incurred in connection with the sales of FINISHED PRODUCTS:

(I) any statutory or contractual liability for rebates to be paid to any governmental entity including, but not limited to, rebates to be paid pursuant to the Medicaid Rebate legislation and state and local government rebate programs;

(II) cash discounts made at the rate in effect at the time of sale;

(III) any adjustments accrued for: allowances or credits for returned FINISHED PRODUCTS, free FINISHED PRODUCTS, damaged FINISHED PRODUCTS, commercial rebates, or trade discounts, whether or not such commercial rebates, or trade discounts are paid directly to the customer and any adjustment granted for any brokerage fees paid;

(IV) the sum of two percent (2%) of gross sales to reflect the cost of handling, distribution including freight, and insurance;

(V) any sales, use, excise or similar taxes or duties included in the gross sales price involved.

1.18 PARTY (PARTIES) shall mean BAYER and/or FIRST HORIZON

1.19 PATENTS means those patents and patent applications covering PRODUCTS and FINISHED PRODUCTS in the TERRITORY including, but not limited to, those listed in Appendix 2, and any and all reissues, reexaminations, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations, continuations-in-part or divisions of or to any of the aforesaid patents or patent applications.

1.20 PRODUCTS shall mean the pharmaceutical preparation in bulk tablets containing Nisoldipine (INN) as the sole active ingredient as specified in Appendix 1 hereto.

1.21 PURCHASED AMOUNT means the amount of PRODUCTS purchased by FIRST HORIZON from BAYER or a third party appointed by or affiliated with BAYER.

1.22 REGULATIONS shall mean regulations and guidelines adopted or promulgated pursuant to the ACT.

1.23 QUALITY AGREEMENT shall mean the Quality Assurance Agreement to be entered into between BAYER and FIRST HORIZON prior to the EFFECTIVE DATE and made an integral part of this AGREEMENT.

1.24 SERIOUS ADVERSE EVENT (SAE) shall mean any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse [21 CFR Parts 20, 310, 312, 314, and 600-Expedited Safety Reporting Requirements for Human Drug and Biological Products; Federal Register Vol. 62, No. 194, pp. 52237-52253; Tuesday, October 7, 1997.]

1.25 SPECIFICATIONS shall mean the specifications for PRODUCTS attached hereto as Exhibit 1.

1.26 TECHNICAL INFORMATION means proprietary materials, documents, data and other scientific, medical and technical information, including all pre-clinical and clinical testing and studies, including, but not limited to, all data or information, whether or not published, regarding procedures, tests, dosage, criteria for patient selection and safety and efficacy and other study protocols, validation reports now owned or hereinafter acquired by BAYER, or which BAYER does not own, but is entitled to transfer, or thereafter acquired with the right to transfer by either PARTY and related to Nisoldipine, PRODUCTS and FINISHED PRODUCTS to the extent relevant for the execution and performance of the AGREEMENT. TECHNICAL INFORMATION shall comprise, but shall not be limited to documentation and data required for the quality control of FINISHED PRODUCT, as contemplated in the QUALITY AGREEMENT and the NDA including SPECIFICATIONS and Packaging Information for FINISHED PRODUCTS. TECHNICAL INFORMATION shall not include pricing, marketing or promotional information developed by FIRST HORIZON except as may be required pursuant to Article 10.

1.27 TERRITORY shall mean the United States of America and its territories and possessions, including Puerto Rico.

1.28 \$US means United States Dollars, the official currency of the United States of America.

ARTICLE 2  
APPOINTMENT

2.1 BAYER hereby appoints FIRST HORIZON exclusively to have PRODUCTS packaged and to sell and distribute FINISHED PRODUCTS in the TERRITORY under the provisions, terms and conditions

stipulated in this AGREEMENT and with the reservations made hereinafter. FIRST HORIZON accepts the appointment and undertakes to safeguard BAYER's interests in every reasonable respect and, in particular, to use COMMERCIALY REASONABLE EFFORTS to promote the sale of FINISHED PRODUCTS in the TERRITORY. BAYER during the term of this AGREEMENT shall not directly or indirectly sell or cause any third party to sell FINISHED PRODUCTS or PRODUCTS in the TERRITORY.

FIRST HORIZON undertakes to promote the FINISHED PRODUCTS with COMMERCIALY REASONABLE EFFORTS in a priority consistent with FIRST HORIZON's practice for products coming from FIRST HORIZON'S own research and development.

2.2 BAYER hereby grants to FIRST HORIZON the exclusive right and license, including the right to grant sublicenses, in the TERRITORY, to use, have used, package, and have packaged, sell, and have sold PRODUCTS and FINISHED PRODUCTS under the PATENTS and the TECHNICAL INFORMATION. In accordance with Article 2.1 above, FIRST HORIZON shall promote, sell and distribute the FINISHED PRODUCTS in the TERRITORY as a distributor, namely in its own name and on its own account.

2.3 In consideration for the rights and the APPOINTMENT granted under this Article 2, FIRST HORIZON shall pay to BAYER, within thirty (30) days after EFFECTIVE DATE, the sum of Ten Millions Dollars (\$US 10,000,000) (the "Lump Sum Payment").

2.4 Following the initial transfer of TECHNICAL INFORMATION to FIRST HORIZON from BAYER and/or AZ, the PARTIES shall thereafter during the term of this Agreement mutually exchange available TECHNICAL INFORMATION.

#### ARTICLE 3 SALE OF OTHER PRODUCTS

3.1 While this Agreement is in effect, the representation and sale of any pharmaceutical product containing Nisoldipine other than PRODUCTS or FINISHED PRODUCTS pursuant to this AGREEMENT may be undertaken by FIRST HORIZON in the TERRITORY only after having obtained BAYER's prior written approval in each individual case, which consent shall not unreasonably be withheld or delayed.

#### ARTICLE 4 NDA/TECHNICAL INFORMATION

4.1 During the term of this AGREEMENT each PARTY will update the TECHNICAL INFORMATION as soon as such update is available to the respective PARTY. The PARTIES shall discuss the legal consequences of such updates and their impact to the NDA.

4.2 BAYER and FIRST HORIZON shall in advance communicate with each other in respect of future clinical studies relating solely to the PRODUCT or FINISHED PRODUCT in the TERRITORY. BAYER and FIRST HORIZON shall have the right to comment on such future clinical studies of the other PARTY.

4.3 Within thirty (30) days after the DATE OF AGREEMENT the parties shall each appoint a medical affairs liaison ("the MEDICAL AFFAIRS LIAISON") to communicate with each other regarding information required to be furnished by each party pursuant to this Article 4.

**ARTICLE 5**  
**REPORTING OF ADVERSE EVENTS/RECALL**

**5.1 Adverse Event Reporting**

Each PARTY shall ensure that, in the marketing of the PRODUCTS and the FINISHED PRODUCTS all AE's and SAE's are recorded, investigated, summarized and reviewed.

With regard to information required pursuant to this Article, each PARTY shall report to:

for BAYER:

Bayer AG  
Pharmaceuticals Business Group  
Global Drug Safety (GDS)  
Tel.: + 49-202-36-8034  
Fax: + 49-202-36-8228  
E-mail: gds.ae-managementteam@bayer-ag.de

for FIRST HORIZON:

First Horizon Pharmaceutical Corporation  
660 Hembree Parkway, Suite 106  
Roswell, GA 30076, USA  
Attn: Director of Regulatory Affairs  
Tel.: +1-770-442-9707  
Fax: +1-770-442-9594

In order that each PARTY may be fully informed of the hereinabove referred experiences, each PARTY shall report hereunder to the other PARTY all SAEs and AEs occurred anywhere in the world. Either PARTY may change its information for notice under this Section by written notice to the other PARTY.

**5.1.1 Serious Adverse Events (SAEs)**

BAYER and FIRST HORIZON shall use the CIOMS-I form or Form FDA 3500A as standard for expedited SAE reporting. Each PARTY shall use all reasonable efforts to exchange SAE information by e-mail.

**Clinical Trials**

All SAEs shall be reported within such timeframe as to allow BAYER or

FIRST HORIZON sufficient time to evaluate, process and comply with worldwide regulatory requirements; FIRST HORIZON shall report within two (2) calendar days for fatal or life-threatening AE reports (initial and follow-up) and within four (4) calendar days for all other serious AEs of receipt of the information by FIRST HORIZON or any agent of FIRST HORIZON to BAYER. BAYER will send the assessed report from these events to FIRST HORIZON within day six (6) from clock start for fatal or life-threatening AEs and on day thirteen (13) for all other SAEs for notification to the FDA of the TERRITORY. All other SAEs from in or outside the TERRITORY will be notified by BAYER to FIRST HORIZON for information only.

#### Spontaneous reports

All SAEs shall be reported within such timeframe as to allow BAYER or FIRST HORIZON sufficient time to evaluate, process and comply with worldwide regulatory requirements; FIRST HORIZON shall report usually within four (4) calendar days for SAE reports (initial and follow-up) of receipt of the information by FIRST HORIZON or any agent of FIRST HORIZON to BAYER. BAYER will send the assessed report to FIRST HORIZON on day thirteen (13) for notification to the National Health Authorities. All other SAEs from in or outside the TERRITORY will be notified by BAYER to FIRST HORIZON for information only.

#### 5.1.2 Non-Serious Adverse Events

##### Clinical Trials

Non-serious AEs are sent after termination of the clinical trial within the clinical trial report without delay, that is, immediately after completion of the clinical trial report.

##### Spontaneous Reports

Non-serious AEs from spontaneous source are sent as separate line-listing within the respective "Periodic Safety Update Report" (see 5.1.3.).

#### 5.1.3 Periodic Safety Update Report (PSUR) and Safety Requests from Health Authority

##### PSURs

BAYER and FIRST HORIZON shall use the ICH format as standard for the compilation of PSURs [ICH Topic E 2 C; Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs; Step 4, Consensus Guideline, 6 November 1996; Note for Guidance on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (CPMP/ICH/288/95); Date for coming into operation: 18 June 1997]. BAYER and FIRST HORIZON shall provide each other with copies of all PSURs at time of submission. During the preparation of the report, if significant safety issues arise, BAYER and FIRST HORIZON will telephone each other in order to discuss these issues. The agreed reporting intervals for PSURs are periodically according to the legal requirements by BAYER to submit a PSUR in the TERRITORY and to ensure that FIRST HORIZON will be able to fulfill the legal requirements for the NDA renewals in the TERRITORY in a timely manner.

##### Safety Requests from Health Authorities

BAYER and FIRST HORIZON shall immediately provide each other with copies of the Health Authority requests. Proposed answers will be exchanged between PARTIES before submission. The answer will be submitted by the PARTY who initially received the request from the Health Authority.

#### 5.1.4 Complaints and Regulatory Actions

Each PARTY shall promptly notify the other PARTY of any complaints received by it in sufficient detail and in sufficient time to allow such PARTY to comply with any and all applicable laws and regulations imposed upon it. Without prejudice of the provisions of Article 4 hereinunder, BAYER shall also advise FIRST HORIZON of any regulatory action (e.g. proposed labeling or other registrational dossier changes, and recalls) which would affect any PRODUCT and/or FINISHED PRODUCT in any country. These procedures may be modified from time to time by written agreement of the PARTIES.

5.1.5 FIRST HORIZON and BAYER agree to consult in general no less frequently than annually on the need for changes in the particular appearance in labeling of packaging and containers of FINISHED PRODUCTS or in the FINISHED PRODUCT information supplied to end users, the medical profession or patients.

In addition to the annual review an emergency review can be implemented at any time at the request of FIRST HORIZON or BAYER. FIRST HORIZON and BAYER agree to negotiate in good faith to their mutual benefit with respect to such changes and FIRST HORIZON shall promptly, in advance, communicate to BAYER the basis for any proposed changes to the local label in the TERRITORY and BAYER shall have the right to comment on any such changes in advance. In addition, BAYER shall be able to propose changes to the local label in the TERRITORY for FIRST HORIZON's consideration.

5.1.6 BAYER and FIRST HORIZON shall keep each other informed in advance of any scheduled meetings or discussions with regulatory authorities that involve product safety. Each PARTY shall cooperate with the other by providing, promptly upon request, the appropriate statistics concerning FINISHED PRODUCT use so as to permit calculations of increased frequency of AEs as required by actual regulations and laws.

5.1.7 Articles 5.1.1 through 5.1.7 may be modified through written agreement of the PARTIES to this AGREEMENT as necessary to assure that both PARTIES are able to comply with worldwide regulations. Safety information involving other formulations of Nisoldipine marketed by BAYER or agents of BAYER anywhere in the world, e.g., immediate release shall be provided by BAYER if required by the ACT and REGULATIONS (e.g. 21 CFR, part 312 and 314.80).

## 5.2 Product Recall

5.2.1 In the event that either PARTY decides for a medical reason at its free discretion or the FDA requires a recall, or takes any other action, in connection with FINISHED PRODUCTS promoted by FIRST HORIZON, FIRST HORIZON shall effect such recall. However, if a recall of FINISHED PRODUCTS is to be effected upon the discretion of either PARTY, the PARTY desiring to initiate the recall shall thoroughly consult with the other PARTY prior to the recall, to the extent reasonably possible under the circumstances.

5.2.2 In the event that any FINISHED PRODUCTS are recalled as a result of an event that is attributable to an act or omission of BAYER, BAYER shall bear all costs and expenses of such recall, including, without limitation, expenses or obligations to third parties, the cost of notifying end users and costs associated with shipment of any recalled FINISHED PRODUCTS from end users and destruction of such FINISHED PRODUCTS.

5.2.3 In the event that any FINISHED PRODUCTS are recalled as a result of an event that is attributable to an act or omission of FIRST HORIZON,

then FIRST HORIZON shall bear all costs and expenses of such recall, including, without limitation, expenses or obligations to third parties, the cost of notifying end users and costs associated with shipment of any recalled FINISHED PRODUCTS from end users and destruction of such FINISHED PRODUCTS.

5.2.4 In the event a recall of FINISHED PRODUCTS is necessary for reasons attributable in part to each of the PARTIES, then FIRST HORIZON and BAYER shall be responsible for a proportionate share of such recall costs to be agreed between FIRST HORIZON and BAYER.

5.2.5 In the event of a recall of FINISHED PRODUCTS, each PARTY shall cooperate in a manner which is appropriate and reasonable under the circumstances. Each PARTY shall notify the other as soon as possible but in no event later than (a) forty-eight (48) hours after receipt of any contract or communication from the FDA or other governmental or regulatory authority in the Territory and (b) five (5) business days after receipt of any contract or communication with any other third party in the Territory which in any way suggests the need for a recall of the Finished Product or otherwise calls into question the quality or safety of the Finished Product.

5.3 FIRST HORIZON shall maintain complete and accurate records for such periods as may be required by the ACT and the REGULATIONS, but in no event for less than three (3) years for all FINISHED PRODUCTS sold by it, including distribution data related to sales of FINISHED PRODUCTS to end users by lot number; provided that in satisfying its obligations under this Section 5.3, FIRST HORIZON may rely on the records of BAYER, as manufacturer, and other third parties to the extent such reliance is reasonable.

5.4 FIRST HORIZON shall be entitled to discontinue its distribution and sale of FINISHED PRODUCTS or to take other reasonable action, in case that new toxicity and/or safety findings or side effects of PRODUCTS or FINISHED PRODUCTS shall occur that are so severe as to warrant such discontinuation or other action. If FIRST HORIZON deems it necessary to stop marketing FINISHED PRODUCTS in the TERRITORY because of the reasons mentioned above, the PARTIES will analyze the situation and will try to find an amicable solution. If, however, BAYER does not reasonably agree with FIRST HORIZON's decision to discontinue permanently the distribution of FINISHED PRODUCTS, FIRST HORIZON, if requested by BAYER, will use COMMERCIALLY REASONABLE EFFORTS to sell its rights under this AGREEMENT including the NDA in the TERRITORY without any charge to BAYER. BAYER will indemnify FIRST HORIZON for all loss, damage, cost or expense reasonably incurred by FIRST HORIZON, including reasonable attorneys' fees, arising out of or relating to PRODUCTS or FINISHED PRODUCTS manufactured, marketed or sold by BAYER or a partner of BAYER in the TERRITORY after receipt of FIRST HORIZON's notice of discontinuation.

5.5 Except as may be expressly provided in this Agreement including without limitation any indemnification obligations hereunder, no claim for compensation, losses or damages including incidental or consequential damages may be made between the PARTIES hereto under this AGREEMENT as a result of any act arising under this Article 5.

ARTICLE 6  
SUPPLY AND PURCHASE

6.1 FIRST HORIZON shall purchase from BAYER and BAYER shall sell to FIRST HORIZON FIRST HORIZON's requirements according to FIRST HORIZON's orders of PRODUCTS.

6.2 The PRODUCTS shall be manufactured, stored and shipped by BAYER in accordance with all applicable LAWS and in accordance with the SPECIFICATIONS and cGMP. BAYER represents and warrants that the SPECIFICATIONS comply in all material respects with all applicable FDA rules and regulations. Except as required by any appropriate GOVERNMENTAL AUTHORITY, such SPECIFICATIONS shall remain the same throughout the term of this Agreement unless any change thereof is mutually agreed to in writing by both PARTIES hereto and approved by the FDA and any other appropriate GOVERNMENTAL AUTHORITY. The PARTIES will report such change as required by the FDA and/or any GOVERNMENTAL AUTHORITY of the TERRITORY. Unless otherwise specifically required by LAW, all such changes to the SPECIFICATIONS shall be approved in writing by each of the PARTIES at least sixty (60) days prior to their implementation.

6.3 Subject to Section 6.4, in the case where BAYER selects a third party to manufacture, analyze or store PRODUCTS, BAYER will commit such third party to the supply provisions of this AGREEMENT and the QUALITY AGREEMENT and shall be fully responsible for the proper compliance of such entity.

6.4 In case of BAYER's intended election of a third party for the manufacture, analysis or storage of PRODUCTS for use in the TERRITORY this election shall be executed only following consultation with and written approval of FIRST HORIZON, which approval shall not unreasonably be withheld; provided, however, that any such third party must provide FIRST HORIZON, prior to undertaking any responsibility from BAYER, with evidence, reasonably satisfactory to FIRST HORIZON, that it has obtained any and all FDA and other GOVERNMENTAL AUTHORITY approvals necessary to provide any of the services to be delegated to it by BAYER.

#### ARTICLE 7 FORECASTS AND PURCHASE ORDERS

7.1 BAYER, agrees to manufacture and supply such quantities of the PRODUCTS as are specified in the Despatch List submitted by FIRST HORIZON in accordance with Article 7.5.

7.2 On the EFFECTIVE DATE and thereafter during the first ten (10) working days in each calendar month FIRST HORIZON shall provide BAYER with a forecast of FIRST HORIZON's requirement for each presentation of the PRODUCTS, including resale and sample quantities, in respect of each of the following twelve (12) months. BAYER shall use all reasonable endeavors to meet FIRST HORIZON's request and in any event shall give notice to FIRST HORIZON within thirty four (34) days of receipt of the forecast of its ability to meet the forecast.

During the first two (2) weeks of July in each calendar year FIRST HORIZON shall submit to BAYER its non binding midterm forecast of FIRST HORIZON's estimated requirement for each presentation of the PRODUCTS for the following [five (5) years] or the remaining portion of this AGREEMENT, whichever is

shorter. Such annual forecast will be broken down to calendar quarters for the calendar year to follow.

7.3 If FIRST HORIZON wishes to increase its requirements of the PRODUCTS between agreed forecasting updates beyond those limits referred to as 'OP' and binding in Article 7.5 or below those referred to in Article 7.5 under 'FP' and 'PL', FIRST HORIZON shall provide BAYER with an ad hoc revision to forecast outlining FIRST HORIZON's new requirements. BAYER shall use its COMMERCIALY REASONABLE EFFORTS but is not committed to meet FIRST HORIZON's request and in any event shall give notice to

FIRST HORIZON within two (2) weeks of receipt of the ad hoc revision to forecast of its ability to meet the new requirement.

7.4 FIRST HORIZON respects the need to ensure manufacturing stability at BAYER and undertakes to provide a schedule (the "Despatch List") with clearly defined manufacturing orders, including, but not limited to, delivery dates, delivery destinations, shipping instructions and any special handling requests. The Despatch List will also identify the following:

'OP' Open Manufacturing orders required for delivery in the following four (4) months. These orders are fixed.

'FP' Firm Planned orders scheduled for delivery in months five (5), six (6) and seven (7), to follow. These are orders which have high probability of remaining firm at subsequent updates, eventually becoming 'OP' orders. FIRST HORIZON shall be obligated to purchase at least 70% of its forecast 'FP' orders and BAYER shall be obligated to supply up to 130% of such orders unless otherwise agreed.

'PL' Planned Orders scheduled for delivery in months eight (8), nine (9), ten (10), eleven (11) and twelve (12). These are provisional orders which are likely to materialize as 'FP' orders but the quantity and timing may be different at each scheduled update. FIRST HORIZON shall be obligated to purchase at least 50% of its 'PL' orders and BAYER shall be obligated to supply up to 150% of such orders, unless otherwise agreed.

7.5 BAYER shall deliver FIRST HORIZON's requirements of PRODUCTS to FIRST HORIZON nominated delivery points within the period defined and confirmed by BAYER as 'OP' according to Article 7.5 above.

7.6 BAYER shall schedule its production to enable BAYER to deliver to FIRST HORIZON's requirements of the PRODUCTS on or before the delivery date as notified in the relevant Despatch List mentioned in Article 7.5 above and confirmed by BAYER according to Articles 7.3 and 7.4.

7.7 BAYER shall regard each "OP" manufacturing order as notified in the relevant Despatch List mentioned in Article 7.5 above to be a firm purchase order of FIRST HORIZON's requirements. Orders in respect of PRODUCT to be used for samples shall be separately identified from orders of PRODUCT for resale.

7.8 FIRST HORIZON shall express its requirements to BAYER [in thousands ("000's) of tablets and kilograms] of PRODUCT (one kg representing an amount of tablets of each presentation of PRODUCT as determined in Appendix 3). Shipments will be made by BAYER only on the basis of the kg-amount indicated by FIRST HORIZON.

7.9 In case BAYER cannot, e. g. due to FORCE MAJEURE (as defined in Article 21.1), fulfill 'OP' or 'FP' orders placed by FIRST HORIZON within FIRST HORIZON's forecast to the full extent or in the delivery time agreed, BAYER shall

use all COMMERCIALY REASONABLE EFFORTS to fulfill such orders to the maximum extent possible such that manufacture of PRODUCTS is accorded at least as much significance by BAYER as if PRODUCTS were to be manufactured and sold solely for BAYER's account. Such efforts shall include, but shall not be limited to, allocating such raw materials or manufacturing capacity as may be available to BAYER pro rata among all products manufactured by BAYER at the site at which the PRODUCTS are manufactured based upon previous usage of such raw materials or manufacturing capacity in the preceding

twelve (12) months or in the case of inability to perform during the first twelve months of this AGREEMENT, based upon forecasted usage.

**ARTICLE 8**  
**SHIPPING TERMS/NON-CONFORMING PRODUCTS**

8.1 All shipments of PRODUCTS shall be made by BAYER CIF to a destination nominated by FIRST HORIZON(INCOTERMS 2000).

8.2 BAYER shall provide to FIRST HORIZON at the time of each shipment of PRODUCTS a certificate of analysis as specified in the QUALITY AGREEMENT for each batch of PRODUCTS shipped.

8.3 Non-Conforming PRODUCT

8.3.1 FIRST HORIZON shall inspect each shipment of PRODUCT received hereunder as soon as practicable following receipt thereof. FIRST HORIZON shall be deemed to have accepted delivery of the PRODUCT in good order and condition, unless FIRST HORIZON has notified BAYER in writing of any short delivery or nonconformity in respect of a shipment of PRODUCT with thirty (30) days following receipt of same. Notwithstanding the foregoing, in the case of any nonconformity which is not readily apparent or discoverable upon reasonable inspection within such thirty (30) day period, any claim of nonconformity with respect thereto shall not be deemed waived and delivery of the PRODUCT shall not be deemed to have been accepted if FIRST HORIZON notifies BAYER as soon as practicable, but no later than fifteen (15) days, following the date on which FIRST HORIZON learns of such nonconformity.

8.3.2 Any claim of nonconformity hereunder shall be accompanied by a report of analysis of the allegedly nonconforming PRODUCT, which report shall be prepared by or on behalf of FIRST HORIZON. If, after analyzing a sample of such PRODUCT, BAYER, confirms FIRST HORIZON's claim of nonconformity, BAYER shall, replace the nonconforming PRODUCT with conforming PRODUCT at BAYER's expense. Pursuant to written directions from BAYER, FIRST HORIZON shall either return the nonconfirming PRODUCT to BAYER, or destroy same, in each case, at BAYER's expense. If BAYER's analysis does not confirm FIRST HORIZON's claim of nonconformity, the PARTIES shall commence good faith discussions with a view to resolving the issue. In the event the issue cannot be resolved within thirty (30) days following the start of such discussions, a sample of the PRODUCT in dispute shall be submitted to an independent laboratory, mutually accepted by the PARTIES, for testing. The results of such testing shall be binding upon the PARTY. The PARTY whose assertion as to the PRODUCT in question was not borne out by the results of the testing by the independent laboratory shall bear all costs relating to such testing.

8.3.3 Notwithstanding anything to the contrary contained in this Article 8, BAYER's warranties and indemnification obligations hereunder for latent defects of PRODUCTS shall survive the failure by FIRST HORIZON to reject

any shipment of PRODUCT.

[\*\*\*] - CONFIDENTIAL TREATMENT REQUESTED

ARTICLE 9  
PURCHASE PRICE/PAYMENT

9.1 The purchase price per tablet of PRODUCTS ordered by FIRST HORIZON (hereinafter "PRICE") shall be initially set by the PARTIES and shall be in effect for PRODUCTS ordered for delivery to FIRST HORIZON on a calendar year basis. The PRICE shall be paid in Euros. The PRICE is determined by the PARTIES on the basis of estimated NET SALES of FINISHED PRODUCTS.

9.2

9.2.1 The PARTIES agree that until December 31st, 2003, the PRICE for PRODUCTS shall be fixed at Euro [\*\*\*] per tablet. Thereafter, the PRICE for PRODUCTS shall be the greater of EURO [\*\*\*] per tablet or [\*\*\*] of NET SALES, as determined for the 12-month-period from December 1 to November 30th of the preceding calendar year (hereinafter MEASUREMENT PERIOD) for which the Purchase Price is being set, divided by the number of tablets sold in the MEASUREMENT PERIOD, but only if the resulting price is more than five (5)% greater than EURO [\*\*\*]; provided, however, that in the event a generic equivalent to the PRODUCTS has been introduced or is expected to be introduced in the forecasted calendar year, then the PARTIES shall meet and renegotiate the Purchase Price in good faith.

9.2.2 FIRST HORIZON shall, by January 15th of 2004 and thereafter by January 15th of each succeeding calendar year, provide BAYER the NET SALES price per tablet of the MEASUREMENT PERIOD. together with an explanation of such calculation.

9.2.3 Unless BAYER raises significant complaints for such calculation within fourteen (14) days of receipt thereof, such NET SALES price calculation shall be the basis for the PRICE in the calendar year following the MEASUREMENT PERIOD. If no agreement can be reached between the PARTIES on such calculation on the NET SALES price, it is agreed that half of the difference between the current PRICE and the new estimated NET SALES price provided by FIRST HORIZON shall be added to the current PRICE and shall prevail for the following year.

9.2.4 The new PRICE shall be effective on a calendar year basis.

9.3 The PRICE shall never be below Euro [\*\*\*] per tablet of PRODUCTS and is hereinafter referred to as the FLOOR PRICE (except as may be agreed to by the PARTIES pursuant to the last proviso of Section 9.2.1).

9.4 If BAYER, in its reasonable judgment, determines that an audit

of FIRST HORIZON's books and records relevant to NET SALES is necessary to verify the payments made by FIRST HORIZON as provided above, then BAYER's designee, provided such designee is (i) a chartered public accountant and (ii) reasonably acceptable to FIRST HORIZON, shall have the right, at BAYER's cost and after reasonable notice to FIRST HORIZON, to perform an audit of the relevant books and records of FIRST HORIZON relating to the PRODUCTS once each year. Before beginning such audit, BAYER's designee shall execute an undertaking, in a form reasonably acceptable to FIRST HORIZON, providing that such auditor shall keep strictly confidential all information reviewed during such audit, provided that it may disclose to BAYER its conclusions regarding

[\*\*\*] - CONFIDENTIAL TREATMENT REQUESTED

any payments owed to or by BAYER. FIRST HORIZON shall receive a copy of such auditor's report promptly after it is completed. If such auditor determines that payments are owed to BAYER, FIRST HORIZON shall pay net the additional amounts and the costs and expenses of the BAYER designee within 30 days of the date such auditor's written report is delivered to FIRST HORIZON. If the auditor determines that FIRST HORIZON's payments are in excess of those required under this AGREEMENT, BAYER shall remit the difference net to FIRST HORIZON within thirty (30) days of the date such auditor's report is delivered to BAYER.

9.5 The PRICE for PRODUCTS shall be paid by FIRST HORIZON against invoices supported by shipping documents and such payments will be made net within sixty (60) days after receipt of invoice.

9.6 In the event of late payment of all or part of the PRODUCTS invoiced by BAYER to the FIRST HORIZON an interest for late payment at an annualized rate of five (5) percentage points above the European Inter Bank Offering Rate (EURIBOR) of the unpaid price or part of such price shall be automatically due and become payable by the FIRST HORIZON without further notice.

9.7 Success Fee

9.7.1 Should the NET SALES during any 12-month period within the term of the AGREEMENT surpass US\$ [\*\*\*] FIRST HORIZON shall pay a one-time success fee of US\$ 10,000,000 (ten million) to BAYER. Each calendar month FIRST HORIZON shall provide BAYER with a monthly report of NET SALES within forty-five (45) days following each calendar month. Such report shall also cover the NET SALES of the past 12 month period to verify whether the payment stipulated according to this Article 9.6.1 is due. Such payment shall be due within fifteen (15) days following the receipt of the first monthly report of NET SALES of the past twelve months above US\$ [\*\*\*].

9.7.2 FIRST HORIZON is only entitled to withhold from the LUMP SUM PAYMENT and the success fee payable to BAYER under Article 9.7.1 the taxes levied or assessed thereon in as far as BAYER shall receive a tax-credit for such payments in the Federal Republic of Germany.

FIRST HORIZON shall provide BAYER as soon as reasonably practicable with certified tax receipts required by the German tax authorities for the taxes deducted from the payments hereunder and paid to the tax authority.

Each PARTY undertakes to cooperate with the other PARTY to achieve within the regulatory provisions being applicable the tax arrangements which are most favorable for both PARTIES.

9.7.3 In no event shall FIRST HORIZON be obligated to pay BAYER any amounts in connection with the sale of inventory of FINISHED PRODUCTS

or PRODUCTS which FIRST HORIZON acquired from AZ.

[\*\*\*] - CONFIDENTIAL TREATMENT REQUESTED

ARTICLE 10  
WARRANTED MINIMUM PURCHASES

10.1 FIRST HORIZON commits itself to purchase from BAYER the following minimum quantities of PRODUCTS for packaging into FINISHED PRODUCTS for commercial sale equivalent to the total annual value according to the PRICE (as determined in Article 9) in each 12-month period commencing with the month (which first month shall consist of any partial month in which the first commercial sale takes place plus the entire following month) of the first commercial sale of PRODUCT by FIRST HORIZON (hereinafter referred to as COMMERCIAL YEAR):

COMMERCIAL YEAR	1	2	3
4	5 -----	-----	-----
-----	-----	-----	-----
Total paid amount for [***] [***] PRODUCTS purchased from BAYER in USD	[***]	[***]	[***]

PURCHASED AMOUNTS in any COMMERCIAL YEAR which are in excess of the foregoing minimum purchases of PRODUCTS for such COMMERCIAL YEAR may, at FIRST HORIZON's option, be applied to satisfy the minimum purchase requirements for subsequent years(s).

10.2 In the event FIRST HORIZON's PURCHASED AMOUNTS in any of the given years should fall short of the warranted figures above, the PARTIES within 45 days following the expiry of the respective year shall convene and shall analyse the reasons for such shortfall and any strategies to regain performance. In determining whether FIRST HORIZON has satisfied its obligations to purchase minimum quantities of PRODUCT, both PARTIES shall discuss in good faith the amount of credit, if any, to be given to FIRST HORIZON against the minimum purchase requirements set forth in Article 10.1 for COMMERCIAL YEAR 1 for the inventory levels of PRODUCTS and FINISHED PRODUCTS that FIRST HORIZON purchased from AZ based upon historical inventory levels consistent with ordinary course of business. For avoidance of doubt, unless FIRST HORIZON has failed to use COMMERCIAL REASONABLE EFFORTS to promote the sale of FINISHED PRODUCTS, such shortfall of sales shall not be deemed to be a breach of this AGREEMENT.

10.3 Subject to Section 10.4, in the event that FIRST HORIZON'S PURCHASED AMOUNTS in any of the given years should fall short of the minimum purchases as contemplated in the preceding Article 10.1, FIRST HORIZON shall pay to BAYER the difference between the sum of purchases of PRODUCTS actually made and the minimum purchases as defined in Article 10.1.

Such payment shall be due to BAYER within six (6) weeks following the lapse of any of the given years.

10.4 FIRST HORIZON's commitment in Article 10.1 is contingent upon:

(I) BAYER's compliance with all material terms of this AGREEMENT;

(II) BAYER fulfilling all FIRST HORIZON supply orders pursuant to the terms hereunder,

(III) the FINISHED PRODUCTS not being withdrawn from the TERRITORY;

[\*\*\*] - CONFIDENTIAL TREATMENT REQUESTED

(IV) no unexpected and significant deterioration in the demand for FINISHED PRODUCTS occurring due to events beyond the reasonable control of FIRST HORIZON including, but not limited to, the introduction of a generic equivalent to the FINISHED PRODUCT;

(V) there not having been any recall of the PRODUCT or FINISHED PRODUCT.

ARTICLE 11  
NEW FORMS OF PRODUCTS

11.1 If, during the term of this AGREEMENT, BAYER plans to introduce inside or outside the TERRITORY a new form of products which contains Nisoldipine, BAYER shall notify FIRST HORIZON of its plans to introduce such new form and, unless BAYER is legally (as opposed to contractually) prevented to provide an offer, FIRST HORIZON shall be entitled to distribute such new form in the TERRITORY on terms to be negotiated in good faith by the PARTIES. If the PARTIES are not able to negotiate terms agreeable to both within six (6) months of BAYER's first notification to FIRST HORIZON, and FIRST HORIZON is not then in compliance with the minimum purchase requirements set forth in Article 10 above, BAYER shall be free to offer such PRODUCTS to third parties on terms no more favorable to such third party than have been previously offered to FIRST HORIZON.

11.2 FIRST HORIZON may, at its option, but with the express prior written approval of BAYER, which will not be unreasonably withheld, finance clinical trials to obtain FDA-approval for new cardiovascular indications for the PRODUCTS (for example, angina). Should FIRST HORIZON receive a NDA-approval for a new indication, then FIRST HORIZON shall be entitled to deduct from its annual payments to BAYER in each of the five calendar years following such approval, (i) ten percent (10%) of the reasonable external costs incurred by FIRST HORIZON in obtaining such approval (as evidenced by invoices from third parties) ("External Costs") plus, (ii) an additional 2.5% of such External Costs (intended to compensate FIRST HORIZON for internal costs), provided that the maximum deduction by FIRST HORIZON in any year shall be limited to \$[\*\*\*]. The data created by FIRST HORIZON hereunder shall form TECHNICAL INFORMATION to which BAYER will have access, and under which BAYER will acquire a perpetual license with the right to sublicense, free of any charge, for use outside the TERRITORY.

ARTICLE 12  
SAMPLES/PACKAGING LOSSES

12.1 Any quantities of PRODUCTS shipped by BAYER and used by FIRST HORIZON for sampling in the TERRITORY shall be sold by BAYER to FIRST HORIZON at a price to be determined separately with the amounts.

12.2 Packaging



12.2.1 BAYER agrees to cover any losses, up to a maximum of 2.5% (two point five percent) of the PRODUCTS, which FIRST HORIZON incurs during packaging of PRODUCTS to FINISHED PRODUCT in a calendar year provided FIRST HORIZON properly evidences such losses. Together with the calculation to be given to BAYER according to Article 9.2.2 FIRST HORIZON will substantiate the losses of production it incurred in the preceding year and the reasons for such losses. The losses shall be accounted for in a reconciliation process to be agreed between the PARTIES.

12.2.2 Any packaging losses exceeding the percentage above will be fully born and absorbed by FIRST HORIZON. FIRST HORIZON however may purchase PRODUCTS to recover such additionally evidenced losses by purchasing PRODUCTS from BAYER at the price prevailing for samples, as referred to above in Article 12.1, provided however such additional losses do not exceed (5%) five percent of the total quantity of PRODUCTS which FIRST HORIZON packages into FINISHED PRODUCTS during a calendar year. However; during the first year after launch of FINISHED PRODUCT such allowance shall be increased to (7.5%) seven point five percent.

#### ARTICLE 13 CONFIDENTIALITY

13.1 During the term of this AGREEMENT and for a period of five (5) years following its termination, the PARTIES shall each hold in confidence all COMMERCIAL INFORMATION and TECHNICAL INFORMATION received from the other PARTY shall have first given the other PARTY hereunder or under the Confidentiality Agreement dated December 4th, 2001 (which is hereby terminated insofar as such agreement relates specifically to the TERRITORY) and any other confidential research, development or business information which may be received from the other PARTY related to the subject matter of this AGREEMENT and shall use the same only for the purpose of this AGREEMENT, except for (and subject to the express provisions of this AGREEMENT otherwise)

(A) information which must be disclosed to competent government agencies;

(B) information which is or becomes part of the public domain through no fault of the recipient or its AFFILIATES;

(C) information which was known by the recipient as shown by the written records of the recipient at the time of its disclosure to the recipient hereunder;

(D) information which is disclosed with the prior written approval of the supplier of such information;

(E) information which becomes known to a PARTY from a source other than the other PARTY hereunder without breach of this AGREEMENT by the recipient, provided that such other source has the right to disclose such information;

(F) information which is disclosed pursuant to the order or requirement of a court, administrative agency, or other governmental body provided, however, the disclosing PARTY reasonable notice of such order so as to allow such other PARTY an opportunity to seek a protective order or similar relief with respect to the information required to be disclosed; and

(G) information which is independently developed by the recipient as shown by the written records of the recipient.

13.2 BAYER shall ensure that COMMERCIAL INFORMATION is not disclosed to employees or agents of BAYER or its AFFILIATES in the TERRITORY, including Bayer Corporation, which employees have marketing or strategic responsibility for BAYER's products sold in the TERRITORY under the name Adalat CC, provided, however, BAYER shall be permitted to disclose, on a need to know basis, to such employees of BAYER or direct affiliates, net proceeds to BAYER under this AGREEMENT.

#### ARTICLE 14 PRODUCT LIABILITY

14.1 BAYER shall indemnify and hold harmless FIRST HORIZON, its AFFILIATES and officers, agents, directors, employees, attorneys, representatives, successors and assigns (collectively "FIRST HORIZON INDEMNITEES") from and against any and all damages, liabilities, settlement costs, expenses, defense costs and reasonable attorney's fees resulting from claims or actions for death or personal injury arising from, or relating to the PRODUCTS or FINISHED PRODUCTS and which are due to:

(I) the negligent acts or omissions of BAYER or any third party subcontractor of BAYER; or

(II) the willful misconduct of BAYER or any third party subcontractor of BAYER; or

(III) any breach by BAYER or any third party subcontractor of BAYER of its obligations pursuant to this AGREEMENT or the QUALITY AGREEMENT provided however, that the FIRST HORIZON INDEMNITEES shall permit BAYER's attorneys, at BAYER's cost and upon BAYER'S acknowledgement of its indemnification obligations, to handle and control the defense and settlement of any claims or suits covered by this indemnity clause. The FIRST HORIZON INDEMNITEES shall provide reasonable cooperation to BAYER in the defense of any such claims or suits, including, but not limited to, affording BAYER complete access to all relevant records. If any FIRST HORIZON INDEMNITEES receive notice of any such claims or complaints, they will promptly notify BAYER thereof. Nothing herein shall prevent the FIRST HORIZON INDEMNITEES from retaining counsel of their choice, at their expense, to monitor the defense, trial or settlement of any indemnified matter and BAYER will reasonably cooperate with such counsel.

14.2 If a claim is brought by FIRST HORIZON against BAYER under Section 14.1 such claim in no event shall contain claims for FIRST HORIZON's own consequential or indirect consequential damages (e.g. loss of profit). Such claims hereby are expressly excluded between the PARTIES.

ARTICLE 15  
WARRANTIES/INDEMNIFICATION

15.1 FIRST HORIZON represents and warrants that the execution, delivery and performance of this AGREEMENT is within the corporate powers of FIRST HORIZON and has been duly authorized by all necessary corporate action. BAYER represents and warrants that the execution, delivery and performance of this AGREEMENT is within the corporate power of BAYER and has been duly authorized by all necessary corporate action. Each PARTY represents and warrants to the other PARTY that this AGREEMENT constitutes a valid and binding AGREEMENT between it and the other PARTY.

15.2 FIRST HORIZON represents and warrants that there are no legal or contractual prohibitions or impediments preventing it from entering into or performing under this AGREEMENT. BAYER represents and warrants that there are no legal or contractual prohibitions or impediments preventing it from entering into and performing under this AGREEMENT.

15.3 FIRST HORIZON and BAYER each undertakes to the other (during the manufacturing, shipping, packaging, marketing and sale of PRODUCTS and/or FINISHED PRODUCTS as respectively appropriate) to strictly adhere to all applicable LAWS and regulations with respect to the PRODUCTS and FINISHED PRODUCTS including, without limitation, the ACT and the REGULATIONS.

15.4 BAYER represents and warrants that as of the DATE OF AGREEMENT:

(I) there is neither inside nor outside the TERRITORY any action, suit, investigation or proceeding, pending or threatened against BAYER relating to the manufacture, sale or use of the PRODUCTS or the FINISHED PRODUCTS; and

(II) the FINISHED PRODUCTS and the PRODUCTS have received all necessary approvals under the ACT and REGULATIONS for sale in the TERRITORY.

15.5 Patents

15.5.1 BAYER represents and warrants that, as of the DATE OF AGREEMENT, to its actual knowledge after due investigation, there are, and as of the EFFECTIVE DATE there will be, no patents owned by others or proprietary rights of others that would be infringed or violated by:

(I) BAYER's sale of the PRODUCTS to FIRST HORIZON as herein provided; or

(II) FIRST HORIZON's exercise of its rights under the APPOINTMENT or its packaging, use or sale of the FINISHED PRODUCTS, within the TERRITORY.

(III) BAYER is and shall be, subject to the provisions of this Agreement, the sole and exclusive owner of the PATENTS all of which are and shall be unencumbered by any liens, security interest or other rights or claims of any third party, and no other person or entity, other than FIRST HORIZON as herein provided, has or shall have any claim of ownership with respect to the PATENTS.

(IV) As of the date hereof, Appendix 2 contains a full and complete list of the PATENTS.

(V) BAYER knows of no fact which does or could materially adversely affect the rights granted to FIRST HORIZON hereunder, including, but not limited to, the rights conferred by the APPOINTMENT.

(VI) Except as expressly set forth herein, BAYER makes no other warranties with respect to the PATENTS, the TECHNICAL INFORMATION or otherwise.

15.6 Each of the representations and warranties made by the PARTIES as set forth in Section 15.1 through 15.5 shall be reconfirmed by the PARTY making it as of the EFFECTIVE DATE, such reconfirmation to be evidenced by a certificate to such effect executed by a duly authorized officer and delivered to the other PARTY on the EFFECTIVE DATE.

15.7 FIRST HORIZON shall indemnify and hold harmless BAYER, its AFFILIATES, and their respective officers, agents, employees, directors, attorneys, representatives, successors and assigns (collectively, "BAYER INDEMNITEES") from and against any and all damages, settlement costs, defense costs and reasonable attorney's fees which the BAYER INDEMNITEES become legally obligated to pay to the extent that such arise out of:

(I) a breach by FIRST HORIZON of any representation or warranty under Articles 15.1; 15.2; and 15.3;

(II) the packaging, labeling, handling, storage, promotion, or distribution by FIRST HORIZON of the FINISHED PRODUCTS; or

(III) any negligent acts or omissions of FIRST HORIZON in the performance of this AGREEMENT, provided however, that FIRST HORIZON shall not be required to indemnify the BAYER INDEMNITEES in respect of (ii) above where such liabilities arise out of the negligence or willful misconduct of BAYER and/or any breach by BAYER of its obligations pursuant to this Agreement and provided, further that the BAYER INDEMNITEES shall permit FIRST HORIZON's attorneys, at FIRST HORIZON's cost and upon FIRST HORIZON'S acknowledgement of its indemnification obligations, to handle and control the defense and settlement of any claims or suits covered by this indemnity clause. The BAYER INDEMNITEES

shall provide reasonable cooperation to FIRST HORIZON in the defense of any such claims or suits, including, but not limited to, affording FIRST HORIZON complete access to all relevant records. If any BAYER INDEMNITEES receive notice of any such indemnified claims or complaints, they will promptly notify FIRST HORIZON thereof. Nothing herein shall prevent BAYER INDEMNITEES from retaining counsel of their choice, at their expense, to monitor the defense, trial or settlement of any indemnified matter and FIRST HORIZON will reasonably cooperate with such counsel.

15.8 BAYER shall indemnify and hold harmless the FIRST HORIZON INDEMNITEES, from and against any and all damages, settlement costs, defense costs and attorney's fees which the FIRST HORIZON INDEMNITEES become legally obligated to pay to the extent that such arise out of:

(I) a breach by BAYER of any representation or warranty under Articles 15.1 through 15.5;

(II) the manufacturing and labeling of the PRODUCTS;

(III) any negligent acts or omissions of BAYER in the performance of this AGREEMENT, provided, however, that the FIRST HORIZON INDEMNITEES shall permit BAYER's attorneys, at BAYER's cost and upon BAYER'S acknowledgement of its indemnification obligations, to handle and control the defense and settlement of any claims or suits covered by this indemnity clause. The FIRST HORIZON INDEMNITEES shall provide reasonable cooperation to BAYER in the defense of any such claims or suits, including, but not limited to, affording BAYER complete access to all relevant records. If any FIRST HORIZON INDEMNITEES receive notice of any such claims or complaints, they will promptly notify BAYER thereof. Nothing herein shall prevent the FIRST HORIZON INDEMNITEES from retaining counsel of their choice, at their expense, to monitor the defense, trial or settlement of any indemnified matter and BAYER will reasonably cooperate with such counsel; or

(IV) any action brought by a third party against FIRST HORIZON for any infringement on any patents arising from FIRST HORIZON'S sales of the PRODUCT or FINISHED PRODUCTS.

15.9 If a claim is brought by either PARTY against the other PARTY under this Article 17 such claims in no event shall contain claims for consequential or indirect consequential damages (e.g., loss of profit) which are hereby expressly excluded between the PARTIES.

#### ARTICLE 16 PATENTS

16.1 During the term of this AGREEMENT BAYER shall not enforce any PATENTS against FIRST HORIZON during marketing and sale of FINISHED PRODUCTS made from PRODUCTS procured according to the provisions of this AGREEMENT in the TERRITORY. This shall also apply to customers of FIRST HORIZON in the TERRITORY.

16.2 FIRST HORIZON and BAYER shall each give the other PARTY immediate notice in writing of any known or presumed counterfeits or imitations or infringements upon the PATENTS, and of any infringements by third parties of the benefits accruing to FIRST HORIZON from them. FIRST HORIZON will afford BAYER full cooperation for the protection of PATENTS. In the event that BAYER learns of

any known or presumed counterfeits or imitations or infringements through such notice from FIRST HORIZON or otherwise, BAYER at BAYER's cost shall promptly take such appropriate steps as are determined by BAYER to be necessary in order to protect the interests of the PARTIES hereunder and the benefits accruing to the PARTIES hereunder, provided, however, the institution, prosecution and completion of any and all measures, actions and procedures with respect to alleged infringers of the PATENTS are reserved exclusively for the

decision of BAYER, unless BAYER fails to take action to protect its rights to the PATENTS within 90 days after notice of any such infringement, in which event FIRST HORIZON at FIRST HORIZON's cost shall have the right to take such action as FIRST HORIZON deems necessary to prevent any such infringement and recover any damages realized by or threatened to FIRST HORIZON as a result of such infringement, and BAYER agrees to cooperate with and assist FIRST HORIZON in its so doing.

16.3 If during the term of this AGREEMENT, a patent owned by a third party would, in the opinion of FIRST HORIZON and BAYER, be necessarily infringed by the exercise by FIRST HORIZON of the rights granted hereunder in the TERRITORY, the PARTIES shall confer together with the aim to agree upon the best means to avoid such infringement and to secure FIRST HORIZON's rights hereunder. Notwithstanding the above, BAYER shall indemnify and hold FIRST HORIZON harmless against any and all liability, damage, loss, cost or expense arising out of suits and claims and regulatory actions and proceedings which are based upon allegations of misuse or unauthorized use of any third party patents or TECHNICAL INFORMATION transferred to FIRST HORIZON related to the sale of PRODUCTS or to the resale by FIRST HORIZON of FINISHED PRODUCTS. Should FIRST HORIZON receive notice of any such claim, action, suit or proceeding, FIRST HORIZON will promptly notify BAYER thereof, and at BAYER's cost BAYER shall handle and control such claims or suits in consultation with FIRST HORIZON.

16.4 BAYER shall at its cost maintain the PATENTS in force in the TERRITORY.

16.5 FIRST HORIZON shall provide BAYER reasonable assistance and cooperation in the event BAYER decides to pursue a claim for an extension of the PATENTS in the TERRITORY.

#### ARTICLE 17 HARDSHIP

If as a result of unforeseen events or developments in the external legal, regulatory or commercial environment or through FORCE MAJEURE inequitable hardship is caused for one or both PARTIES which runs counter to the aim of this AGREEMENT and which the one PARTY cannot reasonably and in good faith expect the other PARTY to tolerate, the PARTIES will discuss and seek in good faith to find equitable ways to amend the AGREEMENT in order to re-establish the basic economic balance of this AGREEMENT. The PARTIES shall have ninety (90) days, following receipt of notification that a PARTY wishes to proceed under this Article, to agree to the revised terms for this AGREEMENT. In the absence of an agreement, the PARTIES may submit the dispute to arbitration under Article 20.6.

#### ARTICLE 18 EFFECTIVE DATE, TERM AND TERMINATION

18.1 Prior to the EFFECTIVE DATE, neither PARTY shall have any

obligation or liability hereunder except as provided for in this Section 18.1. Prior to the EFFECTIVE DATE, each PARTY shall use its COMMERCIALY REASONABLE EFFORTS to take or cause to be taken all actions necessary or desirable

to satisfy the conditions set forth in this AGREEMENT and shall cooperate fully with the other in preparing and filing all notices, applications, submissions, reports and other documents that are necessary or desirable to obtain the approval of the respective GOVERNMENTAL AUTHORITY in the TERRITORY with respect to the transactions contemplated hereby.

18.2 This AGREEMENT shall come into effect and full force on the EFFECTIVE DATE for a term of ten (10) years. Thereafter, the AGREEMENT will be automatically extended for consecutive two (2) year periods unless terminated by FIRST HORIZON giving twelve (12) months prior written notice expiring at the end of the initial period or any subsequent two (2) year period. Prior to the commencement of any two (2) year period, the PARTIES may renegotiate the commercial terms of this AGREEMENT according to the then prevailing situation, provided that neither PARTY is obligated to engage in such renegotiation.

18.3 Either PARTY may terminate this AGREEMENT at any time by giving written notice to the other PARTY in the event that:

18.3.1 Any proceeding in bankruptcy or in reorganization (other than internal re-organization) or for the appointment of a receiver or trustee or any other proceedings under a law for the relief of debtors shall be instituted by or against the other PARTY which are not dismissed within sixty (60) days;

18.3.2 The other PARTY defaults in the performance of any material obligations imposed on it by this AGREEMENT and such default is not remedied in all material respects within forty-five (45) days of receipt of written demand from the notifying PARTY to cure the default.

18.4 This AGREEMENT may be terminated by either PARTY if the conditions precedent to EFFECTIVE DATE do not occur by July 1st, 2002.

18.5 If this AGREEMENT is terminated such expiration or termination shall neither release the other PARTY from any obligation to make payments accrued hereunder prior to the date of such expiration or termination and shall not release the PARTIES from the secrecy obligations as provided in Article 13 or the indemnity obligations of Articles 14 and 15. FIRST HORIZON, however, is entitled to sell and/or use all stocks of PRODUCTS received prior to the effective date of termination hereunder.

18.6 If this AGREEMENT is terminated as a result of FIRST HORIZON's breach of this Agreement, FIRST HORIZON shall immediately reassign the NDA-approval No. 20[ ]356 for FINISHED PRODUCTS in the TERRITORY without any charge to BAYER or to a party designated by BAYER. From the effective date of any termination hereunder the PARTIES shall cease to use TECHNICAL INFORMATION or COMMERCIAL INFORMATION received from the other PARTY under this AGREEMENT and, upon request, shall either destroy or return all copies of such TECHNICAL INFORMATION or COMMERCIAL INFORMATION received.

The obligation of confidentiality and non use shall survive the expiration or termination of this AGREEMENT.

18.7 The termination of this AGREEMENT will not influence any license granted to BAYER according to Article 11.2, unless, however, termination of the AGREEMENT has resulted from BAYER's breach of the AGREEMENT.

ARTICLE 19  
MISCELLANEOUS

19.1 Neither PARTY shall be liable to the other for any failure or delay in the performance of any of its obligations under this AGREEMENT for the time and to the extent such failure or delay is caused by riots, civil commotions, wars, hostilities between nations, LAWS, embargoes, actions by any unaffiliated third parties, acts of God, storms, fires, accidents, labor disputes or strikes, sabotage, terrorism, explosions or other similar or different contingencies, in each case, beyond the reasonable control of the respective PARTIES ("FORCE MAJEURE"). The PARTY affected by FORCE MAJEURE shall provide the other PARTY will full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use COMMERCIALY REASONABLE EFFORTS to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If the performance of any obligation under this AGREEMENT is delayed owing to a FORCE MAJEURE for any continuous period of more than six (6) months, the PARTIES shall consult with respect to an equitable solution, including the possible termination hereof.

19.2 Neither PARTY shall be entitled to assign its rights hereunder to a third party, other than an AFFILIATE (provided that such AFFILIATE satisfies any applicable FDA requirements), without the express written consent of the other PARTY hereto which consent shall not unreasonably be withheld. FIRST HORIZON shall notify BAYER, if it assigns to an AFFILIATE of FIRST HORIZON parts of its obligations thirty (30) days prior to such assignment. Such notification shall include the Notice address and the obligation of such AFFILIATE. BAYER may, according to Article 7.3, appoint a third party to manufacture PRODUCTS, provided such third party provides FIRST HORIZON with such evidence as FIRST HORIZON shall reasonably request, that such third party has obtained any and all FDA approvals necessary to provide the manufacturing, responsibilities to be delegated to such third party.

19.3 The invalidity or unenforceability of an Article or any part of an Article of the AGREEMENT in any jurisdiction shall not cause the invalidity of the whole AGREEMENT as to such jurisdiction, and shall not affect the validity or enforceability of such Article or such part of an Article in any other jurisdiction. The PARTIES will replace any Article or part of an Article found invalid or unenforceable with an alternative which should as nearly as possible achieve the PARTIES original intent.

19.4 No amendment of this AGREEMENT shall be valid or binding upon the PARTIES hereto unless made in writing and duly executed on behalf of each PARTY hereto.

19.5 The PARTIES hereto agree that the validity of this AGREEMENT and their respective rights and obligations under it shall be governed by the laws of Germany.

19.6 Both PARTIES are obligated to undertake all reasonable efforts in order to solve in an amicable way any controversy arising in connection with this AGREEMENT.

Any controversy arising in connection with this AGREEMENT which cannot be solved in an amicable way shall be referred to and determined by arbitration by three (3) arbitrators under the Rules of Conciliation and Arbitration of the International Chamber of Commerce. Such arbitration shall be held at the place of jurisdiction (New York/Cologne) of the defending PARTY, in the English language.

19.7 Any notice required to be given hereunder shall be considered properly given if sent by registered letter or telex or telefax, prepaid, to the applicable PARTY at the address set forth below:

Any notice to FIRST HORIZON shall be addressed to:

FIRST HORIZON PHARMACEUTICAL CORPORATION  
660 Hembree Parkway, Suite 106  
Roswell, GA 30070  
Fax No.: 77-442-9594

Any notice to BAYER shall be addressed to:

BAYER AG  
Konzernzentrale RPD-51368 Leverkusen  
Federal Republic of Germany  
Fax No: (214) 30-81146

or to such other address for such PARTY as it shall have furnished in writing to the other PARTY. If sent by mail, the date of receipt shall be deemed to be one week from the date of mailing.

IN WITNESS WHEREOF the PARTIES have caused this AGREEMENT to be duly executed as of the day and year first written above.

Date: December 12, 2001

Date:

BAYER AG

FIRST HORIZON

By: /s/

-----

Its: Legal Department

-----

Europe -----

By: /s/ Mahendra G. Shah

-----

Its: Chief Executive Officer

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APPENDIX 1

Nisoldipine	Coat Core tablet	10 mg
Nisoldipine	Coat Core tablet	20 mg
Nisoldipine	Coat Core tablet	30 mg
Nisoldipine	Coat Core tablet	40 mg

FIRST HORIZON Agreement Appendix 2

Nisoldipine Patents in USA

Subject	Pat.-No.	Appl.-No.	filng date	Expiration	Remarks
Process	4 600 778	591614	20.03.84	20.04.2004	
Coat core tablet	4 892 741	204056	08.06.88	08.06.2008	

\* Filing date of parent application

Appendix 3

Sular CC /Number of tablet per kg

Dosage equivalent to 1 kg (no. of tablets)

10 mg 3.003

20 mg 3.003

30 mg 3.048

40 mg 3.030

220390.3

# **EXHIBIT E**



# FORM 10-K

**SCIELE PHARMA, INC. - SCRX**

**Filed: March 28, 2002 (period: December 31, 2001)**

Annual report which provides a comprehensive overview of the company for the past year

Part III:

Portions of Registrant's Proxy Statement relating to the 2002

PART I

- ITEM 1. DESCRIPTION OF BUSINESS
- ITEM 2. PROPERTIES
- ITEM 3. LEGAL PROCEEDINGS
- ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

PART II

- ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS
- ITEM 6. SELECTED FINANCIAL DATA
- ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF
- ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS
- ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
- ITEM 9. CHANGES IN AND DISAGREEMENTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

PART III

- ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS
- ITEM 11. EXECUTIVE COMPENSATION
- ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT
- ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

PART IV

- ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K
- SIGNATURES
- REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS
- EX-21 (Subsidiaries of the registrant)
- EX-23 (Consents of experts and counsel)

UNITED STATES SECURITIES AND  
EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001.

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 000-30123  
FIRST HORIZON PHARMACEUTICAL CORPORATION  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization) 58-2004779  
(I.R.S. Employer  
Identification No.)

660 HEMBREE PARKWAY  
SUITE 106  
ROSWELL, GEORGIA  
(Address of Principal Executive  
Offices) 30076  
(Zip Code)

Registrant's telephone number, including area code: (770) 442-9707

Securities registered pursuant to Section 12(b) of the Act:

NONE

Securities registered pursuant to Section 12(g) of the Act:

COMMON STOCK, \$.001 PAR VALUE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Common shares of the registrant outstanding at March 25, 2002 were 27,760,092. The aggregate market value, as of March 25, 2002, of such common shares held by non-affiliates of the registrant was approximately \$395,889,684 based upon the last sales price reported that date on the Nasdaq Stock Market of \$21.85 per share. (Aggregate market value estimated solely for the purposes of this report. For purposes of this calculation, all executive officers, directors and 10% stockholders are classified as affiliate status.)

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of Registrant's Proxy Statement relating to the 2002 Annual Meeting of Stockholders are incorporated into Part III of this Form 10-K.

## PART I

## ITEM 1. DESCRIPTION OF BUSINESS

## OVERVIEW

First Horizon Pharmaceutical Corporation is a specialty pharmaceutical company that markets and sells brand name prescription products. We focus on the treatment of cardiovascular, obstetrical and gynecological, pediatric and gastroenterological conditions and disorders. Our strategy is to acquire or license pharmaceutical products that other companies do not actively market and that we believe have high sales growth potential, are promotion-sensitive and complement our existing products. In addition, we intend to develop new patentable formulations, use new delivery methods and seek regulatory approval for new indications of existing drugs. We may also acquire businesses with complementary products or development pipelines consistent with our therapeutic focus.

Large multinational companies dominate the U.S. prescription pharmaceutical market. These companies often divest products which, as a result of consolidation or lack of strategic fit, do not meet the threshold level of sales required for continued marketing and promotion, as these companies continue to focus on drugs with annual sales in excess of \$1 billion. In the last four years, we have acquired and licensed products from AstraZeneca UK Limited, Aventis SA, Bayer AG, Elan Corporation, Pfizer Inc., Sanofi-Synthelabo Inc. and Wyeth. Third parties manufacture all of our products.

Since 1992, we have introduced 17 products. We promote our products through our nationwide sales and marketing force of approximately 160 professionals, targeting high-prescribing cardiologists, obstetricians and gynecologists, pediatricians, gastroenterologists and select primary care physicians. We also contract with third parties to promote our products in order to target a broader number of physicians.

We were incorporated in Delaware in July 1992 as the surviving corporation of a merger between Century Pharmaceutical Corporation and Horizon Pharmaceutical Corporation. Our principal office is located at 660 Hembree Parkway, Suite 106, Roswell, Georgia 30076 and our telephone number is (770) 442-9707. Our corporate Internet address is [www.firsthorizonpharm.com](http://www.firsthorizonpharm.com). We do not intend the information contained on our website to be a part of this Annual Report.

## FIRST HORIZON STRATEGY

We believe that our ability to market, acquire and develop brand name prescription products uniquely positions us to continue to grow. The key elements of our strategy include:

- Increase product sales through targeted promotion. We seek to increase sales by promoting our products to physicians through our nationwide sales and marketing force. We also contract with third parties to promote our products in order to target a broader number of physicians. We recently entered into co-promotion agreements for our Prenate and Nitrolingual Pumpspray products in order to expand our targeted promotion efforts. We also use direct mail and telemarketing to promote our products. As a result of our promotional efforts, prescriptions of our Robinul and Robinul Forte, Tanafed and Ponstel products have grown 51.9%, 41.9% and 47.0%, respectively, from 2000 to 2001 according to IMS Health's National Prescription Audit Plus data.
- Acquire brand name prescription products. We seek to acquire rights to brand name pharmaceutical products that we believe are promotion sensitive, complement our areas of therapeutic focus and have the potential to leverage our sales infrastructure. In connection with our acquisition of products, we also consider barriers to entry for competitive products including patent protection, complexity of manufacturing processes

and patient and physician loyalty. Over the last four years, we have acquired or licensed nine products.

- Develop proprietary products and line extensions. We seek to reduce the costs and risks of development by focusing on drugs that the FDA has already approved. We plan to develop and launch products, including line extensions of our current products, using patent-protected delivery systems or formulations that offer market differentiation and the potential for market exclusivity. Our current development pipeline includes a line extension to Robinul to treat excessive salivation and the development of a product to treat migraine headaches.
- Acquire businesses with products and development pipelines complementary to ours. We regularly review opportunities to acquire businesses that sell products or have products under development that complement our areas of therapeutic focus.

#### PRODUCTS

Most of our products treat recurring or chronic conditions or disorders which result in repeat use over an extended period of time and generate consistent revenue streams. Our key products include:

PRODUCT	YEAR OF THE COMPANY'S INTRODUCTION	PRODUCT USE
Cardiology:		
Sular.....	2002*	Hypertension
Nitrolingual Pumpspray.....	2000	Acute angina
Obstetrics and Gynecology:		
Prenate and Prenate GT.....	2001	Prescription prenatal vitamins
Ponstel.....	2000	Pain and painful menstruation
Pediatrics:		
Furadantin.....	2002	Urinary tract infections
Tanafed DM.....	2002	Allergy and cold with cough
Tanafed Suspension.....	1993	Allergy and cold
Gastroenterology:		
Robinul and Robinul Forte.....	1999	Adjunctive therapy for peptic ulcer

\* Scheduled for second quarter 2002.

#### Sular

We recently acquired certain U.S. rights relating to the antihypertensive prescription medication Sular from AstraZeneca. We also entered into a long-term manufacturing, supply and distribution agreement with Sular's manufacturer, Bayer. Sular is a patented, once-a-day treatment for hypertension that competes in the approximately \$16 billion antihypertensives market. Sular had U.S. sales of \$45.9 million in 2001.

Prior to the acquisition of Sular, our cardiovascular product offering was limited to Nitrolingual Pumpspray, a product for the treatment of acute angina. We believe that Sular will complement our cardiovascular franchise because the physicians who prescribe our Nitrolingual Pumpspray comprise a large part of the target audience for Sular. In addition, many patients who suffer from acute angina also suffer from hypertension. We believe that Sular offers advantages over other antihypertensives based upon its proven efficacy and safety, its demonstrated ability to provide twenty-four hour blood pressure control and its relative value on a cost per day basis as compared to other branded antihypertensives.

Nisoldipine, the active ingredient in Sular, belongs to a group of medicines called calcium channel blockers. Calcium channel blockers prevent calcium from entering certain types of muscle cells. Because the muscle cells need calcium to contract, calcium channel blockers prevent the cells from contracting and cause them to relax. Nisoldipine selectively relaxes the muscles of small arteries causing them to dilate but has little or no effect on muscles or the veins of the heart.

We believe that Sular has not been actively promoted in the U.S. since 1999. Based on management's experience promoting cardiovascular products and the results of market research we conducted, we believe that it is promotion-sensitive. We plan to launch Sular in the second quarter of 2002 and have developed a launch plan that includes:

- Hiring new sales professionals. We are recruiting new sales professionals and district managers and intend to increase the size of our sales organization by approximately 50 individuals by the end of this year to increase our reach to physicians.
- Contracting with an external sales organization. Similar to our promotional strategy for Nitrolingual Pumpspray and Prenate GT, we intend to contract with an external sales organization to increase the number of physicians we reach with direct selling and sampling efforts.
- Training our sales professionals. We have developed and will implement a training program to prepare our sales professionals to promote Sular to targeted physicians. We plan to complete the training of sales personnel by the end of the second quarter of this year. Once we have partnered with an external sales organization, we will also provide training support to our alliance sales force.
- Developing marketing plans. With the assistance of advertising agencies, we are finalizing our key marketing messages for Sular. Once we have completed the marketing strategy, we will produce promotional materials and print advertisements to support our direct sales efforts.

Sular was developed and patented by Bayer and was approved by the FDA in 1995. In 1996, Bayer granted to Zeneca Limited, a predecessor entity to AstraZeneca, the exclusive right to market, distribute and sell products containing nisoldipine, Sular's active ingredient, in the U.S. As part of this transaction, Bayer has granted to us an exclusive ten-year license to its patents and other intellectual property for the sale of Sular in the United States. Bayer has also agreed to supply us with Sular during the term of this license. Sular is protected by Bayer's patent covering the composition of its coat core tablet that expires in June 2008 and its patent covering the Sular manufacturing process that expires in 2004.

#### Nitrolingual Pumpspray

In February 2000, we began marketing Nitrolingual Pumpspray for which we acquired exclusive distribution rights in the United States from Pohl-Boskamp. Nitrolingual Pumpspray is an oral spray of nitroglycerin used for the acute relief or prevention of chest pain associated with angina pectoris that results from heart disease. Pohl-Boskamp holds a patent that was issued in 1993 on the formulation of Nitrolingual that we license. According to the American Heart Association, about 6.2 million Americans suffer from angina pectoris.

The primary competitor to Nitrolingual Pumpspray is nitroglycerin, which is generally prescribed in tablet form. Unlike tablets, which begin to lose their potency immediately upon opening the bottle, Nitrolingual Pumpspray maintains its potency for two years. Further, studies have shown that Nitrolingual Pumpspray provides for more rapid absorption than the tablets. Each metered dose of Nitrolingual Pumpspray provides for consistent delivery of nitroglycerin. Also, unlike the tablets, Nitrolingual Pumpspray requires no special storage or handling to maintain its potency.

**Prenate Advance and Prenate GT**

In August 2001, we acquired the Prenate line of products from Sanofi-Synthelabo, including Prenate GT, which is a line extension to Prenate Advance that is manufactured using a gel-coating applied with a patent protected manufacturing technology. Prenate GT was also reformulated to include additional vitamins. Prescription prenatal vitamins are generally recommended before, during and after pregnancy so that the mother and the fetus receive adequate amounts of essential vitamins and minerals. The Prenate line has been a market leader of prescription prenatal vitamins based upon total prescriptions written. We believe that the advantages of Prenate GT include easier swallowing and masked taste and smell.

**Ponstel**

In April 2000, we acquired exclusive U.S. rights to market, distribute and sell Ponstel from Pfizer. Ponstel is used for the relief of mild to moderate pain for patients 14 years of age and older if therapy will be for less than one week and for primary dysmenorrhea, which is pain associated with menstruation. One class of frequently prescribed pain relievers is nonsteroidal anti-inflammatory drugs, or NSAIDs. Ponstel is a well known NSAID for treating dysmenorrhea and we believe that its advantages are its non-addictive qualities, low stomach-related side effects and efficacy. Primary dysmenorrhea is one of the most frequently encountered gynecological complaints and affects as many as half of postpubescent females.

**Furadantin**

In December 2001, we acquired U.S. rights to Furadantin from Elan. Furadantin is indicated for the treatment of urinary tract infections and is prescribed primarily by pediatricians. We launched Furadantin in January 2002. We believe that Furadantin will complement our Tanafed products which are also primarily prescribed by pediatricians. Furadantin is a product well-suited for children because it is formulated in liquid suspension form and has a fruit-flavored taste. Furadantin contains nitrofurantoin, which has no known bacterial resistance and is not known to cause allergic side effects that are well documented with other antibiotics.

**Tanafed and Tanafed DM**

Tanafed is a liquid cold and allergy product marketed to pediatricians. We believe that pediatricians prescribe Tanafed because it is effective and children prefer its taste. We introduced Tanafed DM, a line extension of Tanafed containing a cough suppressant, in January 2002.

**Robinul and Robinul Forte**

In January 1999, we acquired exclusive U.S. rights to Robinul and Robinul Forte, which is a higher-strength dosage of Robinul, from Wyeth. Both Robinul and Robinul Forte belong to a class of drugs known as anticholinergics that reduce the motion of the gastrointestinal tract and decrease stomach secretions. The FDA has approved both products for use as a therapy in conjunction with other therapeutics in the treatment of peptic ulcers. Compared to other anticholinergics, the Robinul product line has an overall better side effect profile and is longer acting, thereby requiring fewer doses. We are currently developing a line extension and will seek regulatory approval to use the active ingredient in Robinul to treat symptoms associated with the excessive production of saliva. Industry sources estimate that the U.S. market for anticholinergics was \$130 million in 1999.

**Other Products**

In June 2000, we acquired world-wide rights to market, distribute and sell Cognex, as well as rights to a new unapproved controlled release version of Cognex called Cognex CR, from

Pfizer. Cognex is used for the treatment of mild to moderate dementia associated with Alzheimer's disease. Alzheimer's disease is a progressive, degenerative disease that attacks the brain and results in impaired memory, thinking and behavior. According to the Alzheimer's Association, approximately four million Americans have Alzheimer's disease. Cognex is one of only four FDA-approved drug treatments for mild to moderate dementia associated with Alzheimer's disease.

In addition to Tanafed and Tanafed DM, our other products for the treatment of cough, cold and allergy are Defen-LA tablets, Mescolor tablets and the Protuss product line, which includes Protuss liquid, Protuss DM tablets and Protuss-D Liquid.

We sell Zoto-HC ear drops for the treatment of swimmer's ear infections and Zebutal capsules for the treatment of tension headaches. A study has shown that approximately nine out of ten people have at least one headache in any given year. Headaches account for approximately 18 million outpatient visits annually to hospitals and healthcare clinics.

#### REGULATORY CLASSIFICATION

The FDA approved Sular, Furadantin, Cognex, Ponstel, Nitrolingual Pumpspray, Robinul and Robinul Forte based on new drug application submissions. The FDA also approved an abbreviated new drug application for Zebutal. Prenate is a prescription vitamin and does not have an approved new drug application. However, the FDA has not requested a new drug application on the Prenate line of products because of their long marketing history. We believe our other products are classified by the FDA as drugs that may be marketed without submitting safety and efficacy data at this time because of safety data submitted to the FDA at an earlier time.

#### PRODUCT DEVELOPMENT

We seek to maximize the value of drugs by developing new patentable formulations, using new delivery methods and seeking regulatory approval for new indications. Through the use of these distinct formulations and patent-protected delivery systems, we plan to create a marketing advantage over competing drugs. Some of these development projects include line extensions which allow us to extend the life cycles of our products. We expect the strength of extensive literature-based clinical data on the active ingredients in our products under development, current acceptance and usage of the active ingredients in these products by healthcare professionals and the safety profile of the active ingredients in approved products will reduce development costs and risks associated with FDA approval.

We generally seek to contract third parties to formulate, develop and manufacture materials needed for clinical trials and to perform scale-up work. We select third-party contractors that we believe have the capability to commercially manufacture the products. By selecting qualified third parties capable of both developing formulations and providing full-scale manufacturing services, we believe we will be able to shorten development and scale-up times necessary for production. The key advantage to this approach is that the third-party contractor will have the equipment, operational parameters and validated testing procedures already in place for the commercial manufacture of our products. Our management team has experience in selecting and managing activities of third-party contract companies.

#### Migraine Product (FHPC 01)

We are developing a proprietary formulation of a product named FHPC 01 for the treatment of migraine headaches, which contains an active ingredient that is currently approved by the FDA for other indications. We have entered into a development agreement with Penwest Pharmaceuticals Co. to develop the product using Penwest's patented TIMERx controlled-release technology. Penwest has also granted us the right to reference their drug master file as

necessary for us to submit a new drug application for this product. A drug master file is a submission to the FDA, often in support of a new drug application, that companies may use to provide confidential, detailed information to the FDA about facilities, processes or articles used in the manufacturing, processing, packaging and storing of one or more human drugs without disclosure to third parties. We have developed a once a day formulation for this product and we filed an investigational new drug application for this product on February 17, 2000 which has been accepted by the FDA. We have engaged Parexel International to conduct clinical trials for this product. We have completed a Phase I clinical trial for this product. The National Institute of Health estimates that 28 million Americans suffer from migraine headaches. Of these, approximately half suffer from migraines that are moderately to severely disabling. We encounter risks in connection with our proposed development of our FHPC 01 product which are described under "Risk Factors" in our registration statement on Form S-1 filed on March 5, 2002 (Commission File No. 333-83698), as amended (the "Registration Statement").

#### Excessive Salivation Product (FHPC 02)

We are developing a product named FHPC 02 for the treatment of the symptoms associated with the excessive production of saliva primarily in children. This product will be a line extension of our Robinul products. We have entered into an agreement with Mikart to develop a new dosage form and to manufacture the product. On December 29, 2000, we filed an investigational new drug application for this product which has been accepted by the FDA. Excessive salivation, also known as sialorrhea, occurs primarily in patients suffering from cerebral palsy and other neurodevelopmental diseases.

#### SALES AND MARKETING

To maximize the effectiveness of our selling efforts, our sales force targets select specialty physicians and high-prescribing primary care physicians. Our sales force seeks to develop close relationships with these physicians and respond to their needs. During 2001, we expanded our sales and marketing force from approximately 150 to approximately 160 professionals nationwide. We are realigning our sales force into three specialty groups to optimize productivity. The first specialty group, which is currently in place, markets Sular, Nitrolingual Pumpspray, Prenate GT and Furadantin to physicians at teaching hospitals. The second specialty group will market Sular, Nitrolingual Pumpspray and our Robinul products to primary care physicians and cardiologists. The third specialty group will market our Prenate GT, Ponstel, Tanafed, Furadantin and Robinul products to obstetricians and gynecologists, pediatricians and gastroenterologists. We plan to have our sales force realignment completed during the second quarter of 2002. In September 2001, we entered into a co-promotion agreement with Otsuka to co-promote our Nitrolingual Pumpspray product and a separate co-promotion agreement with PDI to co-promote Prenate GT.

We sell our products to pharmaceutical wholesalers (who in turn distribute to pharmacies), chain drug stores, other retail merchandisers and, on a limited basis, directly to pharmacies. For the year ended December 31, 2001, sales to our top four pharmaceutical wholesalers accounted for over 81.9% of all of our sales. The following wholesalers each accounted for 10.0% or more of all of our sales: McKesson Corporation (21.5%), Cardinal Health, Inc. (21.2%), AmerisourceBergen (20.3%) and Bindley Western Industries, a division of Cardinal (18.9%).

We have a group of sales professionals that focuses exclusively on building relationships with managed-care organizations that can be leveraged across markets. We continue to strengthen this group to gain access to formularies and develop long-term working relationships with managed care organizations.

For the years ended December 31, 1999, 2000 and 2001, Nitrolingual Pumpspray accounted for 0.7%, 24.5% and 19.3%, respectively, of our total sales. For the years ended 1999, 2000 and 2001, Robinul and Robinul Forte accounted for 26.1%, 20.0% and 18.1%, respectively, of our total sales. In 1999, 2000 and 2001, the Tanafed line accounted for 24.2%, 22.3% and 28.5%, respectively, of our total sales.

Although our business is generally non-seasonal, sales of certain products, such as cough and cold products, increase slightly between October and March due to the cold and flu season. We expect the impact of seasonality to decrease as we acquire or obtain licenses for products that treat chronic conditions. However, we anticipate that the seasonality may continue to affect sales for the foreseeable future.

#### THIRD-PARTY AGREEMENTS

##### Sular

In March 2002, we acquired exclusive U.S. rights to distribute and sell Sular from AstraZeneca and Bayer. The purchase price under our asset purchase agreement with AstraZeneca was \$155.0 million plus the assumption of certain liabilities, subject to post-closing adjustments. Under the asset purchase agreement, we acquired the regulatory approval to sell Sular in the United States, current inventory, certain intellectual property, marketing materials for the promotion, advertising and marketing of Sular in the United States, study materials relating to clinical studies of Sular, and certain of AstraZeneca's contracts relating to the marketing, sale and distribution of Sular. We must pay AstraZeneca up to an additional \$20.0 million upon achievement of certain sales milestones before the third anniversary date of the closing of the transaction.

We also purchased from Bayer the U.S. trademark for Sular for \$20.0 million. We entered into a ten year agreement with Bayer, which appoints us as the exclusive party to sell and distribute Sular in the United States, provides us with the rights to sell Sular under certain patents and other technical information owned by Bayer, and provides for the manufacture and supply of Sular to us. We must pay Bayer an additional \$10.0 million within 30 days of the closing under the asset purchase agreement with AstraZeneca. We will pay Bayer for the manufacture and supply of Sular on a unit basis. The unit price to us for Sular may adjust after 2003 based upon changes in the net revenue per unit that we recognize in the sale of Sular. We must also pay Bayer an additional \$10.0 million upon the achievement of a certain sales milestone for Sular if a sales threshold is achieved during the ten year term of the agreement. Under this agreement, we must purchase minimum quantities of Sular from Bayer each year and we must obtain the consent of Bayer prior to selling another product containing the active ingredient in Sular.

Subject to obtaining the consent of Bayer prior to conducting clinical trials for new cardiovascular indications for Sular and in the event that we receive a new drug application approval for these new uses, we may deduct a percentage of the costs incurred to obtain such approval, up to a certain amount, from our payments to Bayer under the agreement for five years following such approval. Bayer will have access to any data that we obtain pursuant to such trials and we will grant Bayer a license to use such data outside of the United States at no cost.

##### Nitrolingual Pumpspray

In July 1999, we acquired exclusive U.S. rights to distribute, market and sell Nitrolingual Pumpspray from Pohl-Boskamp beginning on February 1, 2000 for five years plus an additional five-year renewal period subject to establishing mutually acceptable minimum sales requirements. Under the agreement, Pohl-Boskamp supplies us Nitrolingual Pumpspray at prices that decrease as volume purchased in each year increases. We must purchase designated

minimum quantities in each year of the agreement or pay a fee to keep the agreement in effect. We must also pay a royalty on net sales of the product. Also, Pohl-Boskamp can terminate our distribution agreement for Nitrolingual Pumpspray if we do not sell specified minimum quantities of the product each year, if a company with a product competitive with Nitrolingual Pumpspray acquires direct or indirect influence or control over us, or if a significant change in our stockholders occurs so that Kapoor-Pharma Investments and our employees, management, directors, and any of their respective affiliates, do not in the aggregate directly or indirectly beneficially own at least 20.0% of our shares. Our agreement with Pohl-Boskamp prohibits us from selling other products which are indicated for the relief of angina pectoris.

In September 2001, we entered into a co-promotion agreement with Otsuka to co-promote Nitrolingual Pumpspray through its sales representatives and to promote the product on our behalf in exchange for commission and bonus payments based upon net sales made by Otsuka sales representatives. The term of this agreement is through December 31, 2004, subject to annual renewals.

**Prenate Advance and Prenate GT**

In August 2001, we purchased the Prenate line of prescription prenatal vitamins from Sanofi-Synthelabo. We acquired all of Sanofi-Synthelabo's intellectual property, regulatory permits and licenses and contract rights related to Prenate. The purchase price for the acquired assets was \$52.5 million in cash plus the assumption of certain liabilities and payment for product inventory, subject to post-closing adjustments.

We also assumed Sanofi-Synthelabo's Prenate-related contracts, including a contract with Patheon, Inc., to manufacture Prenate Advance tablets and the core tablets for Prenate GT, and a contract with Banner Pharmacaps to manufacture Prenate GT using its patented manufacturing process to create gelatin-enrobed tablets. Banner Pharmacaps has agreed not to use this manufacturing process to make any other prenatal vitamins. The agreement with Patheon is for a term of five years, beginning October 1, 1999. The agreement with Banner Pharmacaps is for a term of five years, beginning May 3, 2001. Under the terms of the supply agreement with Banner Pharmacaps, the Company will pay Banner Pharmacaps a royalty on net sales above a certain amount of net sales.

In September 2001, we entered into a co-promotion agreement with PDI under which it will promote and distribute samples of Prenate GT to specified physicians for specified fees. The initial term of this agreement is through October 14, 2002.

**Ponstel**

In April 2000, we acquired exclusive rights to market, distribute and sell Ponstel in the United States from Pfizer. The total purchase price was \$13.0 million. In April 2000, we also entered into a supply agreement with Pfizer under which Pfizer was to supply us with designated quantities of Ponstel through the expiration of the supply agreement, which occurred on March 31, 2001. Pfizer has continued to supply Ponstel to us under the same terms. We pay Pfizer an agreed upon price for the supply of Ponstel.

In December 2000, we signed an agreement with West-ward Pharmaceuticals to manufacture Ponstel after West-ward obtains FDA approval to manufacture the product. We anticipate that this will occur by the fourth quarter of 2002. This agreement expires in April 2005. We must purchase all of our requirements for Ponstel from West-ward and are subject to minimum purchase requirements. We must pay West-ward a price for Ponstel based on a multiple of West-ward's direct cost of goods sold in the manufacture and supply of the product. In addition, we must pay West-ward milestone payments, as long as no generics have been introduced, upon certain anniversary dates of FDA approval of the manufacture of Ponstel.

by West-ward. West-ward is currently in the process of manufacturing the required pilot batches in order to obtain such approval.

#### Furadantin

In December 2001, we acquired U.S. rights to Furadantin from Elan. The purchase price for the acquired assets was \$15.8 million in cash, subject to post-closing adjustments, the assumption of certain liabilities and payment for product inventory. Under the agreement, we acquired the assets relating to Furadantin, including the new drug application, trademark and related inventory.

In December 2001, we also entered into a supply agreement with Elan to manufacture and supply Furadantin to us through May 3, 2003. Under the supply agreement, we paid an up-front fee of \$200,000.

#### Tanafed and Tanafed DM

In January 1996, we obtained exclusive distribution rights to Tanafed in North America through December 31, 2003 plus an additional seven years at our option from Unisource Inc. The agreement requires us to purchase all of our requirements for Tanafed from Unisource, including at least certain minimum quantities of Tanafed in each year of the agreement.

In December 1998, we entered into an exclusive distribution agreement with Unisource granting us exclusive rights to sell Tanafed DM in North America and for Unisource to supply Tanafed DM to us through December 2005, subject to an automatic seven year renewal. The agreement requires us to purchase all of our Tanafed DM requirements from Unisource and subjects us to minimum purchase requirements. We must pay Unisource for the manufacture and supply of Tanafed DM based upon fixed unit costs.

We entered into a patent license agreement with Jame Fine Chemicals, Inc., a supplier of a raw material for Tanafed, effective January 1, 2000. This agreement grants us a semi-exclusive license to use, sell and distribute finished products containing an active ingredient used in Tanafed. The licensed patent covers the manufacturing process of an active ingredient used in Tanafed. The license continues through the life of the licensed patent, which expires in 2016. We paid an up-front license fee and agreed to pay certain royalties based on net sales of Tanafed at rates which we believe are within industry customary ranges. Another party also has a license for one of the active ingredients in Tanafed.

#### Robinul and Robinul Forte

In January 1999, we acquired exclusive rights in the United States to Robinul and Robinul Forte tablets from Wyeth. We must pay royalties on net sales under our license agreement with Wyeth. We entered into agreements with Mikart, dated April 23, 1999 and January 21, 2001, for Mikart to become qualified under applicable regulations to manufacture and supply our requirements for Robinul. Mikart became qualified by the FDA to manufacture Robinul on December 3, 2001 and began supplying the Robinul products to us in December 2001. Under these agreements, Mikart will manufacture the products for five years from the time Mikart became a qualified manufacturer plus renewal terms of one year until either party elects not to renew. The agreement with Mikart requires that we purchase certain designated minimum quantities.

In January 2002, we entered into a license agreement with Wyeth-Ayerst Canada Inc. and Whitehall-Robins Inc. under which we acquired rights to manufacture, have manufactured for us, market and sell Robinul and Robinul Forte in Canada. When we begin to sell Robinul in Canada, we will pay Wyeth-Ayerst Canada a royalty on net sales of Robinul in Canada.

#### Other Products

In June 2000, we acquired world-wide rights to market, distribute and sell Cognex as well as rights to a new unapproved version of Cognex called Cognex CR from Pfizer. We paid \$3.5 million in cash for Cognex. We must pay Pfizer up to \$1.5 million in additional purchase price if we obtain FDA approval to market Cognex CR in the United States. At this time, we have no intention of seeking FDA approval to market Cognex CR. In the event that we voluntarily stop selling Cognex for 60 days or more, other than for reasons outside our control, the FTC may order that Cognex revert back to Pfizer and be divested by the FTC to another purchaser.

Under the purchase agreement for the Cognex transaction, we are required to pay royalties upon achieving certain net sales levels of Cognex. We do not expect to pay significant royalties in the near future.

The purchase agreement for Cognex provides for a supply agreement under which an affiliate of Pfizer will manufacture and supply to us either Cognex or the active ingredient in Cognex for two years after the Cognex transaction closed in June 2000, subject to a one year renewal. We paid an agreed upon price for the supply of Cognex and the active ingredient. The supply agreement contains designated quantities of Cognex and its active ingredient that Pfizer's affiliate will supply to us and that we must purchase. We plan to secure a replacement manufacturer for Cognex and are currently in negotiations with a potential manufacturer.

Generally, our other products are manufactured under manufacturing and supply agreements which require that we purchase all of our requirements for these products from the manufacturers which are a party to these agreements, including specified minimum purchase quantities of the product for each year. Except for our Defen-LA, Protuss-D and Zoto-HC products, these agreements generally state that the product supplier will provide products only to us.

#### Migraine Product (FHPC 01)

In October 1998, we entered into an agreement with Inpharmakon Corporation in which we acquired rights to the proprietary information for the migraine product FHPC 01 for which we completed Phase I clinical studies and plan to submit a new drug application. The agreement expires on October 31, 2008, but we may renew it indefinitely after expiration. In May 2000, we entered into an amendment to this agreement in which Inpharmakon Corporation released us from all previous claims that Inpharmakon Corporation may have had under the agreement, and deleted the required time within which we must commence clinical trials and file for regulatory approval of the product. Under the amended agreement, we must develop a workable once-a-day formulation for the drug, conduct clinical trials and file for and exert reasonable efforts to obtain regulatory approval for the drug. If we do not obtain regulatory approval of the drug within three years after filing for such approval and thereafter commence and continue to aggressively market and sell the product, Inpharmakon may terminate the agreement. In the event that Inpharmakon terminates the agreement for failure to achieve these milestones, Inpharmakon may purchase rights to develop the drug at our costs to date. We must also pay up to an aggregate of \$950,000 in non-refundable fees to Inpharmakon at various developmental milestones through and including regulatory approval of the product, and, in the event of commercial sales of the product, we must pay royalties at rates which we believe are within industry customary ranges. If we elect to sell the business opportunity to a third party, we must share the proceeds of the sale with Inpharmakon.

In March 1999, we acquired rights from Penwest Pharmaceuticals Co. to use Penwest's TIMERx controlled-release technology to develop FHPC 01. Under the Penwest agreement, we have the right to manufacture, use and sell the developed product in North America and Mexico for a period extending 15 years from the date a new drug application is issued for the product, as well as a license under certain Penwest patents. We must pay Penwest up to an aggregate

of approximately \$2.6 million of non-refundable fees upon achieving specified development milestones through the first anniversary of the first commercial sale of the product following regulatory approval and royalties upon any sales of the migraine product at rates which we believe are within industry customary ranges. Penwest may terminate the agreement in the event we fail to timely achieve designated performance milestones within prescribed time periods including the completion of clinical trials by April 2002, applying for FDA approval of the product within six months after completing clinical trials and commercially launching the product within two months after obtaining FDA approval. Penwest may also terminate the agreement if we fail to either sell specified minimum quantities of the product each year after approval of the product or pay the applicable royalty to Penwest as if we had sold such minimum quantity. While we will not complete clinical trials of our migraine product by April 2002, we are in negotiations with Penwest to extend or eliminate the milestone date in connection with our continuing negotiations to enter into new arrangements for the development of the migraine product. In the event that we are unable to successfully conclude such new arrangements, we may lose our rights to this product opportunity. We can provide no assurance that we will be able to successfully conclude such new arrangements and maintain our rights to this product opportunity.

#### Excessive Salivation Product (FHPC 02)

In January 2001, we entered into a manufacturing and supply agreement with Mikart granting Mikart exclusive rights to manufacture and package our product under development for the treatment of excessive salivation upon approval of the product by the FDA and upon approval by the FDA of the manufacture of the product by Mikart. The term of this agreement expires five years after FDA approval of the new drug application or supplemental new drug application for the product, subject to automatic one-year renewals.

#### MANUFACTURERS AND SINGLE SOURCE SUPPLIERS

We use third-party manufacturers for the production of our products for development and commercial purposes. Given the general under-utilization of resources, the availability of excess capacity for manufacturing in the marketplace and the lower cost of outsourcing, we intend to continue to outsource our manufacturing for the near term.

Our manufacturers manufacture our products pursuant to our product specifications. Our supply agreement with Pfizer for Ponstel expired March 31, 2001. Pfizer has agreed to supply a quantity of Ponstel which we believe is sufficient for our requirements until the third-party with whom we have an agreement becomes qualified to manufacture Ponstel. We believe this will occur by the fourth quarter of 2002. Under some of our agreements, the manufacturers or other third parties own rights to the products that we have under our marketing licenses. We have not entered into agreements for alternative manufacturing sources for any of our products. Our supplier of Sular has patents on the manufacturing process and composition of its coat core tablet. The suppliers of Nitrolingual Pumpspray and the raw materials for our Tanafed products hold patents relating to their respective products. Banner Pharmacaps holds the patent to the gel-coating technology it uses to manufacture the Prenate GT tablets. These patents may provide us with a competitive advantage because the patents create a barrier to entry to other companies that might otherwise seek to develop similar products.

#### TRADEMARKS

Because of the large number of products on the market which compete with our products, we believe that our product brand names are an important factor in establishing product recognition. We have applied for a U.S. trademark registration for the mark First Horizon Pharmaceutical, which is currently under appeal. We also have trademark applications pending for the marks Tanafed DM, Prenate (and Design), and Prenate GT. Our products are sold under

a variety of trademarks registered in the United States, including Mescolor, Protuss, Zoto-HC (and Design), Tanafed, Defen, Zebutal and Furadantin. We own the U.S. rights to the Cognex trademark and its international counterparts, and the trademarks for Sular, Prenate Advance, Prenate Ultra, MicroIron, MicroIron II, Prenate 90 and Ponstel. Further, we have been licensed rights to use the trademarks Nitrolingual and Robinul from Pohl-Boskamp and Wyeth, respectively. We have rights to the TIMERx trademark pursuant to our rights to market the product we have under development with Penwest. Our trademark registrations could be challenged by others which could result in the loss of use of one or more of our trademarks. Maintenance of our trademarks requires that we enforce our rights by preventing infringement by third parties, and we may not have the resources to stop others from infringing our trademarks.

#### PATENTS

We consider the protection afforded by patents important to our business. We intend to seek patent protection in the United States and selected foreign countries where deemed appropriate for products we develop. There can be no assurances that any patents will result from our patent applications, that any patents that may issue will protect our intellectual property or that any issued patents will not be challenged by third parties. In addition, if we do not avoid infringement of the intellectual property rights of others, we may have to seek a license to sell our products, defend an infringement action or challenge the validity of the intellectual property in court, all of which could be expensive and time consuming.

#### Sular

Pursuant to our distributorship agreement with Bayer, we are afforded patent protection arising from Bayer's patent covering the Sular manufacturing process and Bayer's patent covering the composition of Sular's coat core tablet. These patents expire in 2004 and 2008, respectively.

#### Nitrolingual Pumpspray

By virtue of our distribution agreement with Pohl-Boskamp for Nitrolingual Pumpspray, we are afforded patent protection arising from Pohl-Boskamp's 1993 U.S. patent relating to the product. This patent expires in 2010.

#### Tanafed and Tanafed DM

We entered into a licensing agreement with the raw material supplier for our Tanafed products effective January 1, 2000. This agreement grants us a license to market and distribute Tanafed for which the manufacturer has a patent covering the manufacturing process of one of their active ingredients. This patent expires in 2016. In 2001, we filed U.S. patent applications relating to the compositions comprising an active ingredient in Tanafed DM.

#### Cognex

We own certain patent rights relating to the use of an active ingredient in Cognex to treat conditions associated with Alzheimer's disease. The U.S. patents expire from 2006 through 2013.

#### Migraine Product (FHPC 01)

Pursuant to our development agreement with Penwest for a once-a-day migraine product, we are the licensee of certain Penwest patents for the purpose of manufacturing and marketing the product under development. These patents expire from 2008 through 2016.

## Active Ingredient in Robinul and Robinul Forte

In 1999, we filed a U.S. patent application directed to the use of glycopyrrolate for the treatment of certain new indications. Glycopyrrolate is the active ingredient in Robinul and Robinul Forte. We will not pursue patent applications outside of the United States for this use.

## COMPETITION

The market for drugs is highly competitive with many established manufacturers, suppliers and distributors actively engaged in all phases of the business. We believe that competition in the sale of our products is based primarily on brand awareness, price, availability, product efficacy and service. Our brand name pharmaceutical products may be subject to competition from alternate therapies during the period of patent protection and thereafter from generic or other competitive products. Some of our products compete with generic and other competitive products in the marketplace.

We also compete with other pharmaceutical companies for new products and product line acquisitions. These competitors include Forest Laboratories, Inc., Watson Pharmaceuticals, Inc., King Pharmaceuticals, Inc., Shire Pharmaceuticals Group plc, Biovail Corporation and other companies that acquire branded product lines from other pharmaceutical companies.

## GOVERNMENT REGULATION

According to the Federal Food, Drug, and Cosmetic Act ("FDC Act"), all new drugs are subject to premarket approval by the FDA. Applicable FDA law will treat our development of new products and new uses for approved products or the development of any of our line extensions as "new drugs," which requires the submission of a new drug application ("NDA") or a supplemental NDA ("sNDA") (or an abbreviated NDA ("ANDA") if applicable), and approval by the FDA.

The steps required for approval of an NDA or sNDA may include:

- extensive pre-clinical toxicology and pharmacology studies,
- submission to the FDA of an investigational new drug application ("IND"), which must become effective before human clinical trials can be commenced,
- a series of preliminary clinical studies to demonstrate safety (Phase I) and optimal dosing and pharmacologic effects (Phase II),
- adequate and well-controlled human clinical trials (Phase III) to establish the safety and effectiveness of the product,
- submission of an NDA or an sNDA to the FDA (typically six to twelve month internal FDA review cycle),
- presentation of NDA data to an FDA Advisory Panel for its recommendation and
- FDA approval of the NDA or sNDA prior to any commercial sale or shipment of the product.

Pre-clinical studies generally include laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological animal studies, to assess quality and safety and provide a basis for design of the human clinical trials. An applicant submits the results of the pre-clinical studies with chemistry, manufacturing and control information and pharmacology and toxicology data in support of the proposed clinical study design to the FDA as a part of an IND and for review by the FDA prior to the commencement of human clinical trials. Unless the FDA says otherwise, the IND will become effective 30 days following its receipt by the FDA; however, the FDA may place an IND on "clinical hold" until the sponsor

generates and supplies the FDA with additional data, which prohibits the sponsor of the IND from commencing with clinical studies.

Clinical trials involve the administration of the investigational new drug to humans under the clinical study protocols that had been submitted to the FDA in the IND. The conduct of the clinical trials is subject to extensive regulation including compliance with good clinical practices, obtaining informed patient consent, sponsor monitoring and auditing of the clinical, laboratory and product manufacturing sites and review and approval of each study by an Institutional Review Board. Clinical trials are typically conducted in three sequential Phases, although Phases may overlap. In Phase I, the investigational new drug usually is administered to 20-50 healthy human subjects and is tested for safety. Phase II usually involves studies in a limited patient population (50-200 patients) to:

- determine the initial effectiveness of the investigational new drug for specific indications,
- determine dosage tolerance and optimal dosage and
- identify possible adverse effects and safety risks.

When an investigational new drug is found to be effective to that point and to have an acceptable safety profile in Phase II evaluation, Phase III trials are undertaken to further evaluate clinical effectiveness and to further test for safety within an expanded patient population of usually 200 or more patients. The FDA reviews both the clinical plans and the results of the trials and may require the study to be discontinued at any time if there are significant safety issues or lack of efficacy. In some cases, the FDA can request Phase IV clinical studies to be conducted as a condition of approval of the NDA, to be performed after the NDA approval with a timeframe. These studies can be designed to obtain additional safety and efficacy data, detect new uses for or abuses of a drug, or determine effectiveness for labeled indications under conditions of widespread usage. These studies can involve significant additional expenses, and failure to perform these Phase IV studies within the FDA-stated timeframe can result in the FDA withdrawing the NDA approval.

Once the FDA has approved an NDA, the holder of the NDA may request changes to the product or manufacturing through a supplement to the original NDA, termed an sNDA. The format, content and procedures applicable to NDA supplements are generally the same as those for NDAs. However, the only information required in a supplement is that needed to support the requested change. If the NDA or sNDA is based on new clinical investigations that are essential to the approval of the application, other than bioavailability studies, it may qualify for a three-year period of marketing exclusivity, distinct from any applicable patent protection that may exist. In such a case, the FDA may accept for filing, but will not approve a generic product for three years from the date of that application's approval. The FDA may also require user fees in excess of \$300,000 for prescription drug NDAs or sNDAs. Supplements proposing to include a new indication for use in pediatric populations are not subject to user fees.

Another form of an NDA is the so-called "505(b)(2)" NDA, which applicants submit pursuant to Section 505(b)(2) of the FDC Act. This type of NDA permits the cross-referencing of safety and effectiveness studies that the applicant has not conducted or been granted a right of reference by the sponsor of the animal or human studies, submitted in a prior NDA or in the literature which utilized the same drug. In addition, the FDA recommends a 505(b)(2) NDA for a modification, such as a new dosage form or drug delivery form, of a previously approved drug (but not that held by the 505(b)(2) applicant), which requires more than merely bioequivalence data. This 505(b)(2) NDA is similar to a full NDA, except that, under conditions prescribed by the FDA, it may be supported in whole or in part by one or more animal and human study investigations in the originator NDA or those published in scientific literature in lieu of the applicant's clinical trials. We intend to submit this type of NDA

application to market potential product line extensions or new uses of already-approved products. Payment of user fees may also be required by the FDA.

In addition, if we submit a 505(b)(2) NDA or ANDA, the FDA will require us to certify as to any patent which covers the drug for which we seek approval. If there is a patent in existence, a certain type of certification commonly referred to as a "paragraph 4 certification," is made and proper notice to the patent holder of our intent to market the drug is given, and the patent holder makes an infringement claim within a specified time period, then the FDA will not approve our marketing application for 30 months or until the patent litigation is resolved, whichever occurs sooner. In addition, distinct from patent considerations, approval of a generic type of ANDA could be delayed because of the existence of five or three years of marketing non-patent exclusivity afforded by the FDA for the innovator drug or 180 days of non-patent exclusivity afforded to the first applicant to submit an ANDA with a paragraph 4 certification; however, in certain proscribed cases, this non-patent exclusivity may not prevent the submission and approval of competitor applications. A patent holder can, however, sue for infringement under traditional patent law.

The least burdensome application for new drug approval is the ANDA, which may apply to a new drug that is shown to be bioequivalent to a drug previously approved by the FDA for safety and effectiveness and listed as the drug to which bioequivalence must be shown. An applicant may submit an ANDA for products that are the same as an approved originator drug regarding active ingredient(s), route of administration, dosage form, strength and conditions of use recommended on the labeling. The ANDA requires only bioequivalence data and other technical and manufacturing information, but typically no safety and effectiveness studies.

Even after obtaining regulatory approval, such approval may require post-marketing (Phase IV) testing and surveillance to monitor the safety of the product. In addition, the product approval may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. At present, companies cannot export pharmaceutical products that cannot be lawfully sold in the United States unless certain statutorily prescribed conditions are met.

FDA regulations require that we report adverse events suffered by patients, submit new marketing and promotional materials, submit changes we plan to make to the product manufacturing or labeling and comply with recordkeeping requirements and requirements relating to the distribution of drug samples to physicians. In the event that we do not comply with the FDA requirements, the manufacture, sales and distribution of our products may be suspended, and we may be prevented from obtaining FDA approval of new products. We received a FD-483 at the conclusion of a recent FDA inspection that listed observations relating to record keeping and reporting. We submitted a response, and the FDA has replied that the corrective actions appear to address the issues, but will verify the corrections at the next scheduled inspection.

Our third-party manufacturers must adhere to FDA regulations relating to current good manufacturing practice ("cGMP") regulations, which include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned and salvaged products. Ongoing compliance with cGMP procedures, labeling and other regulatory requirements are monitored through periodic inspections and market surveillance by state and federal agencies, including the FDA. It is also our obligation to periodically monitor the FDA compliance of our third-party manufacturers. Failure by our third-party manufacturers to comply with these rules could result in sanctions being imposed, including fines, injunctions, civil penalties, suspension or withdrawal of FDA approvals, seizures or recalls of products, operating restrictions and criminal prosecutions. In addition, we rely upon our third-party manufacturers to

provide many of the documents that we use to comply with our FDA reporting requirements for Prenate, Ponstel, Robinul, Robinul Forte and Nitrolingual Pumpspray.

In addition, we are subject to fees under the Prescription Drug User Fee Act for new drug applications for new drug products and sNDAs for new uses, except that we may qualify for a waiver of the fee for our first new drug application. We will be responsible for paying these fees for NDAs, sNDAs and subsequent submissions, unless we receive approval from the FDA for a waiver, reduction or refund. We are also subject to regulation under other federal and state laws, including the Occupational Safety and Health Act and other environmental laws and regulations, national restrictions on technology transfer and import, export and customs regulations. In addition, some of our products that contain controlled substances, such as Protuss and Protuss-D, are subject to Drug Enforcement Administration requirements relating to storage, distribution, importation and sampling procedures. We have registered with the Drug Enforcement Administration under the Controlled Substances Act which establishes, among other things, registration, security and recordkeeping requirements. We must also comply with federal and state anti-kickback and other healthcare fraud and abuse laws.

In addition, whether or not we obtain FDA approval, we must obtain approval of a pharmaceutical product by comparable governmental regulatory authorities in foreign countries prior to the commencement of clinical trials and subsequent marketing of such product in these countries. The approval procedure varies from country to country, and the time required may be longer or shorter than that required for FDA approval.

#### ORPHAN DRUG DESIGNATION

We may request orphan drug status for some of our products under development. Orphan drug designation may be granted to those products developed to treat diseases or conditions that affect fewer than 200,000 persons in the United States or that affect more than 200,000 persons in the United States and for which there is no reasonable expectation that the cost of developing and making a drug in the United States for such disease or condition will be recovered from sales in the United States of such drug. Under the law, the developer of an orphan drug may be entitled to seven years of market exclusivity following the approval of the product by the FDA, exemption from user fee payments to the FDA and a tax credit for the amount of money spent on human clinical trials. However, we must be the first to receive FDA marketing approval to receive market exclusivity under the orphan drug statute should there be a competitor with a similar molecular entity pursuing the same intended clinical use. Although we may get market exclusivity under the Orphan Drug Act, the FDA will allow the sale of a molecularly equivalent drug which is clinically superior to or a molecular entity different from another approved orphan drug, although for the same indication, during the seven-year exclusive marketing period. It is also possible that a competitor might try to undermine any exclusivity provided by promoting a product for an off-label use that is the otherwise protected product. We cannot be sure that any of our products under development would ultimately receive orphan drug designation, or that the benefits currently provided by this designation, if we were to receive it, will not subsequently be amended or eliminated. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

#### REIMBURSEMENT

Our ability to market our products successfully will depend in part on the extent to which reimbursement for the costs of the products will be available from government health administration authorities, private health insurers and managed care organizations in the United States and in any foreign markets where we may sell our products. Third-party payors can affect the pricing or relative attractiveness of our products by regulating the reimbursement they provide on our products and competing products. Insurance carriers may not reimburse

healthcare providers for use of our products used for new indications. Domestic and foreign government and third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products.

BACKLOG

As of December 31, 2001, we had no material backlog.

INSURANCE

We maintain a product liability insurance policy. We do not maintain separate business interruption insurance, however our property and casualty insurance policy provides for payment for lost inventory and lost sales in the event of loss from damage to our property.

EMPLOYEES

We had 195 full-time employees as of December 31, 2001, including 156 sales and marketing employees in the field and 39 in management, finance and administration. We also maintain active independent contractor relationships with various individuals with whom we have consulting agreements. We believe our employee relations are good. None of our employees is subject to a collective bargaining agreement.

ITEM 2. PROPERTIES

We lease a 24,300 square-foot facility in Roswell, Georgia. Our facility includes space for offices and a warehouse. This lease expires on August 31, 2003. We recently entered into a lease for a 101,120 square foot office and warehouse facility in Alpharetta, Georgia and plan to relocate to this facility in April 2002. This lease expires eight years and one month after we begin occupying the premises.

ITEM 3. LEGAL PROCEEDINGS

On November 7, 2001, Ethex Corporation and Ther-Rx, both Missouri corporations, filed a complaint against us in the Circuit Court of St. Louis County, Missouri. The complaint alleges that we made false and misleading statements about our Prenate products and about Ethex and Ther-Rx's products in the course of our advertising and promotion of the products in violation of the Lanham Act and under Missouri state law. The complaint seeks unspecified monetary damages and an injunction against further violations, certain corrective actions and a declaratory judgment. We plan to vigorously defend this suit. From time to time, we may become involved in routine litigation in the ordinary course of our business. Other than the claim discussed above, we are not a party to any material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our stockholders during the fourth quarter of 2001.

## PART II

## ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock began trading on the Nasdaq National Market on May 31, 2000. Our trading symbol is "FHRX." The following table lists, for the periods indicated, the high and low sale prices per share for our common stock as reported on the Nasdaq National Market.

		HIGH	LOW
		-----	-----
2000			
	Second Quarter (May 31, 2000 through June 30, 2000).....	\$ 7.58	\$ 5.33
	Third Quarter.....	12.54	6.33
	Fourth Quarter.....	20.58	9.00
2001			
	First Quarter.....	\$19.42	\$11.17
	Second Quarter.....	21.40	12.75
	Third Quarter.....	26.03	19.23
	Fourth Quarter.....	30.88	21.07

On September 24, 2001, we completed a three-for-two stock split. The stock split was effected in the form of a stock dividend paid on September 24, 2001 to stockholders of record on September 10, 2001. The high and low sale prices per share of common stock have been retroactively adjusted to reflect the stock split.

On March 25, 2002, the last reported sale price for our common stock on the Nasdaq National Market was \$21.85 per share. As of March 21, 2002, there were approximately 166 holders of record of our common stock.

## DIVIDEND POLICY

We have not declared or paid any cash dividends since our inception. We currently intend to retain our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Our current credit facility prohibits the payment of any dividends or other distributions on any shares of our stock.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data is qualified by reference to and should be read in conjunction with our financial statements and the related notes and other financial information included elsewhere in this Annual Report and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected financial data has been derived from our financial statements which have been audited by Arthur Andersen LLP, independent public accountants. These results may not be indicative of future results.

	YEAR ENDED DECEMBER 31,				
	1997	1998	1999	2000	2001(1)
	(IN THOUSANDS, EXCEPT PER SHARE DATA)				
<b>STATEMENT OF OPERATIONS DATA:</b>					
Net revenues.....	\$ 5,558	\$ 9,252	\$ 18,625	\$ 36,650	\$ 69,290
Cost of revenues.....	1,137	1,903	3,140	5,436	10,354
Selling, general and administrative expense.....	4,679	6,790	12,546	24,217	38,689
Depreciation and amortization expense.....	30	35	424	1,091	2,724
Research and development expense.....	--	255	860	1,784	1,819
Operating (loss) income.....	(288)	269	1,655	4,122	15,704
Interest expense.....	(6)	(13)	(357)	(324)	(4)
Interest income.....	3	4	12	348	1,874
Other.....	4	(3)	8	21	4
Benefit (provision) for income taxes.....	107	(121)	(548)	(1,660)	(6,855)
Net (loss) income.....	\$ (180)	\$ 136	\$ 770	\$ 2,507	\$ 10,723
Net (loss) income per share:	=====	=====	=====	=====	=====
Basic.....	\$ (0.02)	\$ 0.01	\$ 0.06	\$ 0.15	\$ 0.44
Diluted.....	\$ (0.02)	\$ 0.01	\$ 0.06	\$ 0.13	\$ 0.41

(1) We acquired the rights to Prenate and Furadantin in August 2001 and December 2001, respectively. The results of these acquisitions are included in our operating results subsequent to the respective dates of these product acquisitions. In addition, we acquired Sular in March 2002.

	AS OF DECEMBER 31,				
	1997	1998	1999	2000	2001
	(IN THOUSANDS)				

BALANCE SHEET DATA:					
Cash and cash equivalents.....	\$ 245	\$ 425	\$ 220	\$14,228	\$ 53,458
Total assets.....	1,759	2,933	11,078	50,083	170,150
Total debt.....	--	603	3,699	221	--
Total stockholders' equity.....	814	956	3,616	38,572	143,364

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**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and related financial data should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this Annual Report.

**OVERVIEW**

We are a specialty pharmaceutical company that markets and sells brand name prescription products. We focus on the treatment of cardiovascular, obstetrical and gynecological, pediatric and gastroenterological conditions and disorders. Our strategy is to acquire or license pharmaceutical products that other companies do not actively market and that we believe have high sales growth potential, are promotion-sensitive and complement our existing products, in addition, we intend to develop new patentable formulations, use new delivery methods and seek regulatory approval for new indications of existing drugs. We may also acquire businesses with complementary products or development pipelines consistent with our therapeutic focus.

Since 1999, we have acquired or licensed products from AstraZeneca, Aventis, Bayer, Elan, Pfizer, Sanofi-Synthelabo and Wyeth. These acquisitions have included the following: Sular, a hypertension product acquired in 2002, Furadantin, a pediatric urinary tract infection product acquired in 2001, the Prenate line of prenatal vitamins acquired in 2001, Ponstel, a product for the treatment of pain and painful menstruation acquired in 2000, Nitrolingual Pumpspray, a product for the treatment of acute angina acquired in 1999, and the Robinul line of products, an adjunctive therapy for the treatment of peptic ulcers, acquired in 1999.

**IMPACT OF RECENT ACQUISITIONS**

The following discussion compares our results of operations for the years ended December 31, 2001 and December 31, 2000 as reported in our consolidated financial statements included elsewhere in this Annual Report. Our results of operations for 2001 do not include Sular and include Prenate and Furadantin only from August 20, 2001 and December 21, 2001, the respective dates on which we acquired those product lines. On March 5, 2002, we filed the Registration Statement to register 7,475,000 shares of common stock. Included in the Registration Statement is pro forma financial information which contains adjustments to our actual results of operations for 2001 to include the actual operating results of such product lines in those portions of 2001 during which we did not own such product lines, as well as certain other adjustments attributable to such acquisitions. As set forth in the following discussion, we believe that our results of operations for 2001 and the pro forma financial information is not indicative of our future operating results due to our expectations concerning the following:

- increased revenues as a result of completed and pending acquisitions and our promotional efforts,
- decreased overall margins as a result of lower margins on Sular,
- increased selling, general and administrative expense related to promotional efforts for our new products,
- increased depreciation and amortization expense due to completed and pending acquisitions,
- increased interest expense due to the financing of the Sular acquisition with debt and
- reduced interest income as a result of investing a portion of our cash and cash equivalents in product acquisitions.

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## PENDING PUBLIC OFFERING

If completed, estimated net proceeds from the offering described in the Registration Statement would approximate \$133 million based on the sale of 6,500,000 shares of common stock at the public offering price of \$21.75 per share. In general, we intend to use the proceeds from this offering to repay debt incurred to purchase Sular. Further details of the risks involved with this offering, the risks in the event we are unable to complete this offering, the risks that this offering does not generate sufficient proceeds to repay outstanding debt, and the expected use of proceeds can be found in the Registration Statement.

## RESULTS OF OPERATIONS

## YEARS ENDED DECEMBER 31, 2001 AND DECEMBER 31, 2000

Net revenues increased \$32.6 million, or 89.1%, over the year ended December 31, 2000, to \$69.3 million for the year ended December 31, 2001. The increase in sales for the year ended December 31, 2001 was primarily due to increased unit sales of our key products Tanafed, Robinul, Nitrolingual Pumpspray and Ponstel. According to IMS Health's National Prescription Audit Plus data, total prescriptions of Tanafed, Robinul and Robinul Forte and Ponstel increased 41.9%, 51.9% and 47.0%, respectively. While we do not report independent market data on prescriptions of Nitrolingual Pumpspray because we believe such data does not capture prescriptions from some of the non-retail channels, unit sales of Nitrolingual Pumpspray also increased substantially.

Our operating results for the year ended December 31, 2001 include net sales of Prenate Advance and Prenate GT since August 2001. The year ended December 31, 2001 does not include any net sales of Furadantin or Sular. Prior to our acquisitions of the Prenate line, Furadantin and Sular, the Prenate line had U.S. net sales of \$11.0 million for the period of January 1, 2001 through August 20, 2001, Furadantin had U.S. net sales of \$4.4 million in calendar year 2001 and Sular had U.S. net sales of \$45.9 million in calendar year 2001. We began to sell Nitrolingual Pumpspray in February, 2000 and Ponstel in April, 2000.

Cost of revenues increased \$4.9 million, or 90.5%, to \$10.4 million for the year ended December 31, 2001 compared to \$5.4 million for the year ended December 31, 2000. Gross margin for the years ended December 31, 2001 and December 31, 2000 was 85.1% and 85.2%, respectively. Gross margin for the year ended 2001 does not include the impact of Furadantin and Sular. Gross margins are expected to decrease as Sular has previously had a lower gross margin than our other products. Sular had a pro forma gross margin of 74.8% in 2001.

Selling, general and administrative expense increased \$14.5 million, or 59.8%, to \$38.7 for the year ended December 31, 2001. As a percentage of net revenues, selling, general and administrative expenses were 55.8% in 2001 and 66.1% in 2000, representing our ability to leverage our selling, general and administrative expense over a larger sales base. Selling related expense increased in 2001 due to higher commission, royalty and product sampling expense as a result of increased sales and higher advertising, promotion, consulting and market research reporting costs associated with the launch of Prenate GT in September 2001. Selling expense also increased in 2001 due to additional commissions under our co-promotion agreements with PDI and Otsuka for Prenate GT and Nitrolingual Pumpspray, respectively.

Selling expense will increase significantly as a result of the acquisitions of Sular and, to a lesser extent, Furadantin. We will incur significant training, sampling, advertising and promotion

costs during the launch of these products, especially with respect to Sular during our second quarter of 2002. We also expect to incur increased expense in 2002 as a result of our planned expansion of our sales force by up to 50 persons during 2002 and our plans to enter into a co-promotional arrangement with a third party regarding Sular.

General and administrative expense increased for the year ended December 31, 2001 due to additions to our management team and support personnel, and higher insurance costs due to increased insurance coverage. Also included in the 2001 expense were one-time charges of approximately \$250,000 for severance to a departing officer as well as approximately \$300,000 of lease abandonment costs incurred in connection with our move to a new facility. We recently signed a lease for a 101,000 square foot building that we plan to occupy beginning April 1, 2002 which increases the size of our facility by approximately 75,000 square feet. General and administrative expense will increase as a result of the acquisition of Sular due to increases in insurance expense and additional personnel we expect to hire during 2002.

Depreciation and amortization expense increased \$1.6 million, or 149.7%, to \$2.7 million for the year ended December 31, 2001. This increase resulted from higher amortization expense related to the acquisition of Furadantin on December 21, 2001, the Prenate line on August 20, 2001, Ponstel on April 14, 2000, Cognex on June 22, 2000 and increased depreciation expense for furniture, computer equipment and leasehold improvements at the Company's corporate headquarters. Amortization expense for the year ended December 31, 2001 does not include a full year of expense for the Prenate line and Furadantin. It also does not include amortization for Sular. Amortization expense will increase significantly in 2002 and beyond due to the amortization of Sular. During early 2002, depreciation expense will increase due to the accelerated write down of leasehold improvements located in our current facility that we plan to vacate during the second quarter of 2002.

Research and development expense increased \$35,000, to \$1.8 million for the year ended December 31, 2001 compared to \$1.8 million for the year ended December 31, 2000. We continue to incur research and development cost associated with the development of the migraine product and the Robinul line extension. Research and development expense for 2001 does not include expenses related to the Prenate line, Furadantin and Sular. We estimate that our research and development expense through 2003 will be approximately \$6.1 million due to continued development work on our proposed migraine product and Robinul line extension, planned reformulations of Prenate GT and other development initiatives.

Interest expense was \$4,000 for the year ended December 31, 2001 compared to \$324,000 for the year ended December 31, 2000. At December 31, 2001, we did not have any debt outstanding. In March 2002 as part of the Sular acquisition, we incurred \$127.0 million of term debt accruing interest at the Eurodollar rate plus 3.75% and \$10.0 million of revolving debt accruing interest at the Eurodollar rate plus 3.25%. While these amounts remain outstanding under this credit facility, we expect our monthly expense under this credit facility to be approximately \$640,000. In addition to such interest expense, we have incurred various fees and may incur additional fees in connection with this credit facility which will be recorded as interest expense during the period in which borrowings under this credit facility are expected to remain outstanding. These borrowings are expected to be repaid during the second quarter of 2002. These fees will range between \$2.6 million and \$5.1 million depending on the timing of the completion of our pending public offering and the retirement of the term loan as more fully described below under "Liquidity and Capital Resources". We expect to use the proceeds from our pending public offering to retire the term loan and reduce the borrowings under the revolver. If we are unsuccessful in concluding our pending public offering or another equity offering to raise funds sufficient to retire the term loan prior to its maturity date (which occurs in September 2002) and reduce the borrowings under our revolver to not more than \$5.0 million, we will be required to locate other sources of financing to retire such indebtedness and would expect to incur significant additional fees for such purposes.

Interest income was \$1.9 million for the year ended December 31, 2001 compared to \$348,000 for the year ended December 31, 2000. The increase was the result of interest earned on the proceeds of our follow-on offering that we completed in May 2001. We expect our interest income for 2002 to be lower due to our uses of cash for acquisitions completed during 2001 and expected to occur in 2002, and our expected use of most of the proceeds from our pending public offering to retire or reduce the amount of borrowings under our credit facility.

Income taxes were provided for at a rate of 39.0% in 2001 compared to 39.8% in 2000. The decrease is primarily due to state income tax structuring initiatives.

YEARS ENDED DECEMBER 31, 2000 AND DECEMBER 31, 1999

Net revenues increased \$18.0 million or 96.8%, over the year ended December 31, 1999, to \$36.7 million for the year ended December 31, 2000. Sales of continuing products increased \$6.3 million or 34.4% to \$24.4 million for the year ended December 31, 2000. Sales of a discontinued product were \$324,000 for the year ended December 31, 1999. The increase in sales of continuing products was primarily due to higher unit sales of Robinul, Robinul Forte and Tanafed. Sales of Nitrolingual Pumpspray, Ponstel and Cognex, were \$12.2 million for the year ended December 31, 2000. We began to sell Nitrolingual Pumpspray on February 1, 2000 (under a license agreement entered into in 1999), Ponstel on April 14, 2000 and Cognex on June 22, 2000.

Cost of revenues increased \$2.3 million or 73.1%, to \$5.4 million for the year ended December 31, 2000 compared to \$3.1 million for the year ended December 31, 1999. Gross margin for the year ended December 31, 2000 was 85.2% compared to 83.1% for the year ended December 31, 1999. This increase resulted primarily from increased sales of Robinul and Robinul Forte, which have higher margins than our other products, as well as sales of the newly acquired Cognex and Ponstel products, which also have higher margins.

Selling, general and administrative expense increased \$11.7 million, or 93.0%, to \$24.2 million for the year ended December 31, 2000. Selling expense increased due to expansion of our sales force, higher commission expense due to increased sales, increased marketing and promotional expense due to promotional campaigns for new products, increased sampling of our products, increased training expense for new and existing sales representatives and other market research activities. Royalty expense increased due to increased sales of Robinul, Robinul Forte and Zebutal and royalties on sales of Nitrolingual Pumpspray and Tanafed. There was no comparable royalty expense on Tanafed sales in 1999.

General and administrative expense increased due to additions to our management team and support personnel in our corporate office, higher insurance costs due to increased insurance coverage, higher professional fees related to our public reporting requirements, and higher consulting costs.

Depreciation and amortization expense increased \$667,000 or 157.3% to \$1.1 million for the year ended December 31, 2000. This increase resulted from higher amortization expense related to the acquisition of Robinul and Robinul Forte in January 1999, Ponstel on April 14, 2000 and Cognex on June 22, 2000, and increased depreciation expense for furniture, computer equipment and leasehold improvements at our corporate headquarters.

Research and development expense increased \$924,000, or 107.4% to \$1.8 million for the year ended December 31, 2000. This increase resulted from continued development of FHPC 01, our migraine product under development, and the Robinul line extension. In addition, on May 3, 2000, we amended the payment terms under our Collaboration Agreement with Inpharmakon Corporation relating to the development of FHPC 01. Under the amended terms, we paid a \$200,000 fee to Inpharmakon upon completion of our initial public offering.

Interest expense decreased \$33,000, or 9.2%, to \$324,000 for the year ended December 31, 2000.

Interest income was \$348,000 for the year ended December 31, 2000 compared to \$12,000 for the year ended December 31, 1999. The increase was the result of interest earned on the remaining proceeds from our initial public offering which was completed in May 2000.

Income taxes were provided for in the amount of \$1.7 million at a rate of 39.8% in 2000 compared to \$548,000 at a rate of 41.6% in 1999. The decreased rate is primarily due to state income tax structuring initiatives.

#### LIQUIDITY AND CAPITAL RESOURCES

Our liquidity requirements arise from debt service, working capital requirements and funding of acquisitions. We have met these cash requirements through cash from operations, proceeds from our line of credit, borrowings for product acquisitions and the issuance of common stock.

Our cash and cash equivalents were \$220,000, \$14.2 million and \$53.5 million at December 31, 1999, 2000 and 2001, respectively. Net cash provided by operating activities for the years ended December 31, 1999, 2000 and 2001 was \$1.0 million, \$3.3 million and \$24.0 million, respectively. The sources of cash primarily resulted from net income plus non-cash expense and increased accounts payable and accrued expense, partially offset by increases in accounts receivable and inventories. In 2001, our tax liability was reduced by \$8.9 million due to the exercise of non-qualified stock options by employees. Our purchase of inventory impacts our liquidity. During 2002, we expect to invest cash in the purchase of inventory for our recently acquired product lines and expect we will also experience growth in our accounts receivable as we begin to sell these products which are new to us. We believe that our cash on hand, cash we expect to generate from our operations and availability under our revolving credit facility will be sufficient to fund these working capital requirements. While some of our supply agreements contain minimum purchase requirements, these minimum purchase requirements are not material to us as in each case our requirements for inventory substantially exceed such minimum purchase requirements. We expect to use significant cash for operating activities in the future in connection with our development activities. We have estimated that our research and development expenses through 2003 will be approximately \$6.1 million due to continued development work on our proposed migraine product and Robinul line extension, planned reformulations of Prenate GT and other development initiatives.

Net cash used in investing activities for the years ended December 31, 1999, 2000 and 2001 was \$4.2 million, \$17.1 million and \$69.4 million, respectively. In 1999 we purchased the rights to market Robinul and Robinul Forte for \$4.0 million in cash with an additional \$1.8 million financed by the seller, which we paid off in January 2001. In April 2000, we purchased the rights to market Ponstel for \$13.0 million. In June 2000, we purchased the rights to market Cognex for \$3.5 million in cash. In August 2001, we purchased the Prenate line from Sanofi-Synthelabo for \$51.9 million in cash. In December 2001, we purchased Furadantin and completed a supply agreement from Elan for \$16.0 million in cash. In addition, we purchased \$186,000, \$547,000, and \$191,000 of property and equipment in the years ended December 31, 1999, 2000 and 2001, respectively.

Net cash provided by financing activities for the years ended December 31, 1999, 2000 and 2001 was \$3.0 million, \$27.8 million and \$84.6 million, respectively. During 1999, we borrowed \$4.0 million and incurred indebtedness of \$1.8 million for the purchase of intangible assets. In 1999, we also made payments of \$1.2 million on long-term debt and had a net increase of \$197,000 on our revolving line of credit. The primary source of cash in 2000 was from our initial public offering and the exercise of stock options that provided net proceeds of \$31.3 million offset by payment on the revolving loan agreement of \$800,000 and a net repayment of debt of \$2.7 million. For 2001, the source for cash was the Company's follow-on

offering and the exercise of stock options by employees that together provided net proceeds of \$84.8 million offset by a payment of long-term debt of \$221,000.

In January 1999, we borrowed \$2.4 million under a term loan with LaSalle Bank. The term loan bore an interest rate at our choice of either the bank's prime rate or LIBOR plus 2%. On April 14, 2000, the credit facility was further amended to include bridge financing of up to \$13.0 million to finance product acquisitions. On April 14, 2000, we borrowed \$9.5 million under this bridge loan for the purchase of Ponstel. Borrowings under the bridge loan bore interest at our choice of the bank's prime rate or LIBOR plus 1.5%. On June 5, 2000, the outstanding balance under this term loan and bridge loan were paid with proceeds from our initial public offering. On April 14, 2000, we issued a promissory note to Pfizer evidencing \$3.5 million of the purchase price of Ponstel. This promissory note was interest free. We paid this promissory note in full with proceeds from the initial public offering.

On March 5, 2002, we entered into a credit agreement for a senior secured credit facility arranged by Deutsche Banc Alex. Brown Inc. for \$152.0 million consisting of a \$127.0 million term loan and a \$25.0 million revolving loan to fund the purchase of Sular and our working capital requirements. Borrowings under the term loan bear interest at our option at the base rate in effect from time to time plus an applicable margin or the Eurodollar rate, plus an applicable margin. The actual interest rate on the term loan approximates 5.66% based on current Eurodollar rates. The term loan matures in September 2002. We are required to apply our net proceeds from any equity or debt financing, sale of assets and certain other events to repayment of the term loan. Borrowings under the revolving loan bear interest at our option at the base rate in effect from time to time plus an applicable margin or the Eurodollar rate, plus an applicable margin. The actual interest rate on the revolving loan approximates 5.16% based on current Eurodollar rates. The revolving loan matures in March 2005, provided that, in the event the term loan is not repaid in full from the proceeds of one or more stock offerings or other junior financing, on or prior to the term loan maturity date, then the revolving loan will mature on the same date as the term loan. We intend to retire the term loan and reduce borrowings under the revolving loan with the proceeds from our pending public offering. We are required to reduce our borrowings under the revolving loan facility to not more than \$5.0 million concurrently with our retirement of the term loan. However, we may thereafter draw the funds under the revolving facility in accordance with its terms.

In addition to the interest described above, our interest expense while the credit facility is outstanding will include the amortization, over the expected life of the facility, of approximately \$2.5 million of financing fees, \$1.2 million of which was paid in connection with our entering into the definitive agreement to acquire Sular and \$1.3 million which we paid at the time of our acquisition of Sular. In addition, if we are unable to retire the term loan facility prior to certain dates specified in the loan commitment, we will be required to pay additional fees ranging from approximately \$800,000 if such term loan has not been retired by May 1, 2002 to an aggregate of approximately \$2.5 million if such term loan facility has not been retired by August 6, 2002. Other fees payable by us under such credit facility include an annual administrative fee of \$100,000, a commitment fee of 0.75% per annum of the total facility from January 28, 2002 until March 6, 2002 and a fee of 0.75% (0.50% after retirement of the term loan) of the unused portion of the revolving loan facility.

This credit facility contains various restrictive covenants, including covenants relative to maintaining financial ratios and earnings, limitations on acquisitions, dispositions and capital expenditures, limitations on incurring additional indebtedness and a prohibition on payment of dividends and other payments on our common stock. In addition, we are required to raise net proceeds of at least \$30.0 million from an equity financing by June 2002 and apply such net proceeds to repayment of the term loan.

We intend to use the net proceeds from our pending public offering to retire the term loan and reduce the outstanding balance under our revolving loan to not more than \$5.0 million. Assuming we do not use our existing cash to repay any of these borrowings, we estimate that this will require net proceeds of not less than \$132.0 million to retire the \$127.0 million of indebtedness outstanding under the term loan and repay \$5.0 million of the \$10.0 million indebtedness outstanding under the revolving loan. To the extent we draw additional funds under the revolving loan to satisfy our liquidity requirements pending completion of this offering, we will be required to raise additional funds to comply with the requirements of our senior secured credit facility.

Assuming that we are able to successfully complete our pending public offering and raise net proceeds sufficient to retire the term loan and reduce the indebtedness outstanding under the revolving loan to not more than \$5.0 million, management believes that our cash and cash equivalents, cash to be generated from operations and the revolving credit facility under our senior secured credit facility will be adequate to fund our current working capital requirements for at least the next 12 months. However, in the event that we make significant acquisitions in the future, we may be required to raise additional funds through additional borrowings or the issuance of debt or equity securities.

If we are unable to successfully complete our pending public offering and raise net proceeds sufficient to retire the term loan and reduce the indebtedness outstanding under the revolving loan to not more than \$5.0 million, we will be required to locate other means to repay or refinance the indebtedness then outstanding under our senior secured credit facility. We do not currently have a commitment or other means to repay or refinance such facility and we can provide no assurances that we will be able to refinance or repay such facility on acceptable terms, if at all.

#### INFLATION

We have experienced only moderate price increases under our agreements with third-party manufacturers as a result of raw material and labor price increases. We have generally passed these price increases along to our customers.

#### SEASONALITY

Although our business is generally non-seasonal, sales of certain products, such as cough and cold products, increase slightly between October and March due to the cold and flu season. We expect the impact of seasonality to decrease as we acquire or obtain licenses for products that treat chronic conditions. However, we anticipate that the seasonality may continue to affect sales for the foreseeable future.

#### CRITICAL ACCOUNTING POLICIES

We view our critical accounting policies to be those policies which are very important to the portrayal of our financial condition and results of operations, and require management's most difficult, complex or subjective judgments. The circumstances that make these judgments difficult or complex relate to the need for management to make estimates about the effect of matters that are inherently uncertain. We believe our critical accounting policies to be as follows:

- Allowance for doubtful accounts. We are required to estimate the level of accounts receivable recorded in our balance sheet which will ultimately not be paid. Among other things, this assessment requires analysis of the financial strength of our customers, which can be highly subjective, particularly in the recent difficult general economic environment. Our policy is to estimate bad debt expense based on prior experience supplemented by a periodic customer specific review when needed.

- Sales deductions. We provide volume rebates, contractual price reductions with drug wholesalers and insurance companies, and certain other sales related deductions on a regular basis. The exact level of these deductions is not always immediately known and thus we must record an estimate at the time of sale. Our estimates are based on historical experience with similar programs, and since we have a relatively small customer base, customer specific historical experience is often useful in determining the estimated level of deductions expected to be refunded to our customers when sales incentives are offered.
- Product returns. In the pharmaceutical industry, customers are normally granted the right to return product for a refund if the product has not been used prior to its expiration date, which is typically two to three years from the date of manufacture. Management is required to estimate the level of sales which will ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of a given product, all of which have been on the market for many years, product specific information provided by our customers and information obtained from independent sources regarding the levels of inventory being held by our customers, as well as overall purchasing patterns by our customers.
- Intangible assets. When we acquire the rights to manufacture and sell a product, we record the cash purchase price, along with the value of the product related liabilities we assume, as intangible assets. We use the assistance of valuation experts to help us allocate the purchase price to the fair value of the various intangible assets we have acquired. Then, we must estimate the economic useful life of each of these intangible assets in order to amortize their cost as an expense in our statement of operations over the estimated economic useful life of the related asset. The factors that drive the actual economic useful life of a pharmaceutical product are inherently uncertain, and include patent protection, physician loyalty and prescribing patterns, competition by products prescribed for similar indications, future introductions of competing products not yet FDA approved, the impact of promotional efforts and many other issues. We use all of these factors in initially estimating the economic useful lives of our products, and we also continuously monitor these factors for indications of appropriate revisions. See also "Recent Accounting Pronouncements" where we discuss the adoption of SFAS No. 142 in 2002.

#### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141 "Business Combinations". SFAS No. 141 eliminates the pooling-of-interest method of accounting for business combinations. SFAS No. 141 is effective for any business combination completed after June 30, 2001. Management believes that the application of the provisions of SFAS No. 141 will not have a material impact on our financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets". Under SFAS No. 142, goodwill and indefinite lived intangible assets are no longer amortized. Separate intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives. SFAS No. 142 also establishes a new method of testing goodwill and other intangible assets for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that would reduce the fair value of that goodwill or other intangible asset below its carrying value. The amortization provisions of SFAS No. 142 apply to goodwill and other intangible assets acquired after June 30, 2001. Management believes that the application of the provisions of SFAS No. 142 will not have a material impact on our financial condition or results of operations.

In August 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets." SFAS No. 144 addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and is effective for financial periods after January 1, 2002. Management believes that the application of the provisions of SFAS No. 144 will not have a material impact on our financial condition or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS

Our operating results and cash flows are subject to fluctuations from changes in foreign currency exchange rates and interest rates. Our purchases of Nitrolingual Pumpspray under our agreement with Pohl-Boskamp are made in Euros. Our purchases of Sular product inventory from Bayer will be made in Euros. In addition, sales of Cognex are recognized in the foreign currencies of the respective European countries in which it is sold. While the effect of foreign currency translations has not been material to our results of operations to date, currency translations on export sales or import purchases could be adversely affected in the future by the relationship of the U.S. dollar with foreign currencies.

In connection with borrowings incurred under the senior secured credit facility arranged by Deutsche Banc Alex. Brown Inc., we will experience market risk with respect to changes in the general level of the interest rates and its effect upon our interest expense. Borrowings under this facility bear interest at variable rates. Because such rates are variable, an increase in interest rates will result in additional interest expense and a reduction in interest rates will result in reduced interest expense. Accordingly, our present exposure to interest rate fluctuations is primarily dependent on rate changes that may occur while the senior secured credit facility is outstanding.

## FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes" "may," "will," "plan," "intends," "estimates," "could," "should," "would," "continue," "seeks," "pro forma" or "anticipates," or other similar words (including their use in the negative), or by discussions of future matters such as the development of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions "Description of Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this Annual Report.

Such statements include, but are not limited to the following: (i) our ability to acquire or license products, (ii) our ability to develop new formulations, use new delivery methods and seek regulatory approval for new indications of existing drugs, (iii) our ability to acquire other businesses, (iv) that Sular and Furadantin will complement existing products, (v) the success of our launch plans for Sular, (vi) our ability to increase and realign our sales force size and increase the promotional reach for Sular, (vii) our ability to enter into agreements with third-party sales organizations to co-promote our products including Sular, (viii) our ability to implement successful sales force training and marketing plans for Sular, (ix) our ability to increase sales of Sular, Furadantin and Prenate and the effects of the Prenate, Furantin and Sular acquisitions on our operations and financial statements, (x) timely supply to us of Ponstel by our new contract manufacturer, (xi) our ability to obtain regulatory approval for our migraine development product and Robinul line extension, (xii) the expected cost of development for these products, (xiii) our ability to defend and enforce intellectual property rights, (xiv) future amortization and depreciation, research and development, and interest expense, (xv) our ability to satisfy our working capital requirements, (xvi) our ability to repay our debt in a timely manner prior to incurring expensive fees and interest, (xvii) our ability to repay all or a portion of our debt with the proceeds from our pending public offering, (xviii) timing of fees and interest due on our debt and (xix) the adequacy of the current supply of Ponstel.

Such forward-looking statements involve uncertainties and other factors, including those described in the "Risk Factors" section of the Registration Statement under the headings: "We expect our operating results to be substantially dependent upon our results of operations for Sular, and any factor adversely affecting sales of Sular could have a material adverse effect on our sales and profits," "We may have difficulty maintaining or increasing sales of Sular, Prenate and Furadantin and successfully integrating these products into our business," "The costs we may incur to sell our new products may be disproportionately high relative to their expected revenues," "The potential growth rate for Sular may be limited by slower growth for the class of drugs to which Sular belongs," "We have no experience selling Sular, have only limited experience selling Furadantin and the Prenate products and there is no established market for Prenate GT," "The regulatory status of prenatal vitamins may make Prenate products subject to increased competition," "Our level of debt could reduce our growth and profitability," "If we are unable to timely and successfully complete this offering, we will incur additional expenses, may be required to enter into unfavorable financing arrangements, and may have insufficient liquidity to execute our business strategy," "Our growth will suffer if we do not acquire rights to new products and integrate them successfully," "We depend entirely on third parties to

manufacture our products," "We may encounter interruptions in our supply of Ponstel," "We may encounter interruptions in our supply of Furadantin," "Our existing supply agreements may prohibit us from entering into potentially more favorable supply relationships with others," "Part of our growth strategy is to acquire businesses which subjects us to additional risks," "We face competition from generic products that could lower prices and unit sales," "Strong competition exists for our products, and competitors have introduced new products and therapies that could make our products obsolete," "A small number of customers account for a large portion of our sales and the loss of one of them, or changes in their purchasing patterns, could result in reduced sales," "If our products under development fail in clinical studies or if we fail or encounter difficulties in obtaining regulatory approval for new products or new uses of existing products, we will have expended significant resources for no return," "We or third parties may violate government regulations," "If third-party payors do not adequately reimburse patients for our products, doctors may not prescribe them," "We depend on highly trained management, and we may not be able to keep current management or hire qualified management in the future," "Product liability claims and product recalls could limit our ability to sell products," "We expect to require additional funding and if we cannot obtain it, our sales, profits, acquisitions and development projects could suffer," "Competitors could offer a product competitive with Sular," "If we do not secure or enforce our patents or other intellectual property rights, we could encounter increased competition that could adversely affect our operating results," "Our products could infringe the intellectual property rights of third parties, which could require us to pay license fees or defend litigation that could be expensive or prevent us from selling products," "The regulatory status of some of our products makes these products subject to increased competition and other risks," "We face risks under one of our development agreements because the other party to the agreement is a related party," "Pohl-Boskamp can terminate our rights to Nitrolingual," "We have no experience selling products in other countries," "There is uncertainty concerning our continued use of Arthur Andersen LLP as our outside auditor" and "There is uncertainty concerning stockholder approval to increase our authorized common stock." We do not undertake to update our forward-looking statements to reflect future events or circumstances.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is set forth at the pages indicated in Item 14(a) below.

## ITEM 9. CHANGES IN AND DISAGREEMENTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

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## PART III

## ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

Our directors and executive officers are as follows:

NAME	AGE	POSITION
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Mahendra G. Shah, Ph.D.(1).....	57	Chairman of the Board, Chief Executive Officer and President
Balaji Venkataraman.....	35	Executive Vice President, Chief Financial Officer, Chief Operating Officer and Secretary
Christopher D. Offen.....	53	Executive Vice President and Chief Commercial Officer
Robert D. Godfrey, Jr.....	39	Senior Vice President of Sales and Sales Operations
William G. Campbell.....	46	Vice President of Administration, Controller and Treasurer
Andrew D. Shales.....	40	Vice President of Marketing
Michael A. Leone.....	45	Vice President of Sales
Jerry N. Ellis(2).....	64	Director
John N. Kapoor, Ph.D.....	58	Director
Pierre Lapalme(2) (3).....	61	Director
Jon S. Saxe(2) (3).....	65	Director
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(1) Member of Stock Option Subcommittee.

(2) Member of the Audit Committee.

(3) Member of the Compensation Committee.

Mahendra G. Shah, Ph.D. is the Chairman of the Board, Chief Executive Officer and President. Dr. Shah has been a director since 1993, and his present term as director will expire at the annual meeting of stockholders to be held in 2004. Dr. Shah became Chief Executive Officer in October 1999 and President in January 2002. From 1991 to 2000, he was a Vice President of EJ Financial Enterprises, Inc., which manages a fund that invests in healthcare companies. From 1996 to the present, he has been the President of Protomed Pharmaceuticals, Inc., which is a privately-held drug development company. From 1987 to 1991, he was the senior director of new business development with Fujisawa USA, Inc. Prior to that, he worked in various scientific and management positions with Schering-Plough and Bristol-Myers Squibb Company. He serves on the board of Structural Bioinformatics Inc. and Introgen Therapeutics. He was previously Chairman of Inpharmakon Corporation. Dr. Shah received a Ph.D. degree in Industrial Pharmacy from St. John's University. EJ Financial Enterprises, Inc. is the managing general partner of Kapoor-Pharma Investments, L.P., our largest stockholder.

Balaji Venkataraman has been the Vice President and Chief Financial Officer since November 1999. He was appointed as Executive Vice President and Secretary in January 2001 and Chief Operating Officer in January 2002. Between August 1998 and September 1999, he was our Vice President of Corporate Development and Strategic Planning. He also served as a consultant to us during his employment as the Director of Strategic Planning at EJ Financial Enterprises, Inc. from September 1997 to August 1998. From 1995 to 1997, he was Associate, Licensing and New Business Start-up, at the University of Pennsylvania Center for Technology Transfer. From 1994 to 1995, he was the Marketing Manager at Curative Technologies Inc., a wound care services company. From 1993 to 1994, he was a

Technical Sales Representative for

Millipore Corporation. From 1991 to 1993, he was the Senior Research Chemist at Scios Inc. He has also held product management and finance positions at Schering Plough and Pfizer, Inc. Mr. Venkataraman received an M.S. degree in Organic Chemistry from Case Western Reserve University and an M.B.A. degree from the Wharton School of Business at the University of Pennsylvania.

Christopher D. Offen was appointed Vice President and Chief Commercial Officer in January 2001 and Executive Vice President in January 2002. Prior to joining us, from 2000 to 2001, Mr. Offen was Senior Vice President and Managing Director at A.M. Pappas & Associates, an international life science venture capital company. From 1991 through 1999, Mr. Offen was Senior Vice President of Commercial Operations, Vice President of Business Development and Vice President of Marketing of Solvay Pharmaceutical, Inc. From 1971 to 1991, Mr. Offen worked at Burroughs Wellcome Co. (now GlaxoSmithKline). Mr. Offen attended the Advanced Executive Program at the Kellogg School of Business at Northwestern University, received an M.B.A. degree from George Mason University concentrating in Marketing/Management and a B.S. degree in Pre-Medicine from The Catholic University of America.

Robert D. Godfrey, Jr. was appointed as Vice President of Sales in 1998 and Senior Vice President of Sales and Sales Operations in January 2002. He served as the National Sales Manager between 1996 and 1998. He began his career with us in 1992 as a Sales Representative for the Jacksonville, Florida territory and was promoted in 1994 to District Manager of the entire Florida sales territory. At that time, in addition to his managerial responsibilities, he continued to promote our products to physicians and pharmacies until 1995. Prior to his career with us, Mr. Godfrey was a market research consultant with MGT Information Systems. Mr. Godfrey received an M.B.A. degree and a B.S. degree in Marketing from Jacksonville University.

William G. Campbell was appointed as Controller and Treasurer in 1998 and Vice President of Administration in January 2002. Prior to joining us, from 1995 to 1998, Mr. Campbell was the Controller/Chief Financial Officer of DialysisAmerica, Inc. He was the Associate Administrator/Chief Financial Officer of Stringfellow Memorial Hospital from 1993 to 1995, and from 1989 to 1993, he was the Director of Budgets, Costs and Reimbursement at Grady Memorial Hospital. His prior professional experience also includes a number of for-profit and not-for-profit consulting, big five public accounting, governmental auditing and internal audit positions. Mr. Campbell is a Certified Public Accountant and received a B.A. degree in Accounting from Walsh College of Accountancy and Business Administration and an M.B.A. degree in Accounting from Kennesaw State College.

Andrew D. Shales was appointed as Vice President of Marketing in May 2001. From 1997 to May 2001, Mr. Shales held various marketing managerial positions at UCB Pharma, Inc., a global, research-based pharmaceutical company headquartered in Brussels, Belgium. From 1996 to 1997, Mr. Shales directed the marketing of products in the cardiovascular and obesity markets while working at Medeva Pharmaceutical, Inc. Mr. Shales started his career at Solvay Pharmaceuticals, Inc. as a sales representative and also worked as a Market Research Analyst and Product Manager. Mr. Shales graduated from King's College in Wilkes-Barre, Pennsylvania with a B.A. degree in Psychology.

Michael A. Leone was appointed as Vice President of Sales in January 2002. From 1999 to 2000, Mr. Leone was a consultant to a number of biotechnology and pharmaceutical firms, creating strategically aligned sales and managed care organizations and developing customer focused strategies for those organizations. From 1977 to 1999, Mr. Leone worked at E.R. Squibb & Sons, Inc. and Bristol-Myers Squibb Company in positions of increasing responsibility including National Accounts Director, Regional Business Director, and National Director, Federal and Institutional Sales. Mr. Leone received a B.S. degree in Biology from the University of South Florida.

Jerry N. Ellis was elected a director in November 2000. His term as director will expire at the annual meeting of stockholders to be held in 2003. Mr. Ellis has over thirty years of auditing and accounting experience. From 1994 to 2000, Mr. Ellis was a consultant to Arthur Andersen LLP for services focusing on international auditing, audit committee practices, business risk management and training. From 1973 to 1994, he was a partner at Arthur Andersen in their Dallas, Madrid and Chicago offices. From 1962 to 1973, Mr. Ellis was an auditor at Arthur Andersen. Mr. Ellis is a director of Akorn, Inc. and an Adjunct Professor of Advanced Auditing at the University of Iowa. Mr. Ellis is a Certified Public Accountant and received B.B.A. and M.B.A. degrees from the University of Iowa.

John N. Kapoor, Ph.D. has been one of our directors since 1996, and his present term as director will expire at the annual meeting of stockholders to be held in 2003. Dr. Kapoor has over twenty years of experience in the healthcare field through his ownership and management of healthcare-related businesses. In 1990, Dr. Kapoor founded Kapoor-Pharma Investments, L.P., our largest stockholder, and its managing partner, EJ Financial Enterprises, Inc., of which he is the president and sole stockholder. EJ Financial provides general funds and strategic advice to healthcare businesses. Dr. Kapoor is the Chairman of Optioncare, Inc., Akorn, Inc., Introgen Therapeutics, Inc. and Neopharm, Inc. Dr. Kapoor is a Chairman of several private companies and a director of several other private companies. Dr. Kapoor received a B.S. degree from Bombay University and a Ph.D. in Medicinal Chemistry from the State University of New York.

Dr. Kapoor was previously the Chairman and President of Lyphomed Inc. Fujisawa Pharmaceutical Co. Ltd. was a major stockholder of Lyphomed from the mid-1980s until 1990, at which time Fujisawa completed a tender offer for the remaining shares of Lyphomed, including the shares held by Dr. Kapoor. In 1992, Fujisawa filed suit in federal district court in Illinois against Dr. Kapoor alleging that between 1980 and 1986, Lyphomed filed a large number of allegedly fraudulent new drug applications with the FDA, and that Dr. Kapoor's failure to make certain disclosures to Fujisawa constituted a violation of federal securities laws and the Racketeer Influenced and Corrupt Organizations Act. Fujisawa also alleged state law claims. Dr. Kapoor countersued, and in 1999, the litigation was settled on terms mutually acceptable to the parties. The terms of the settlement are subject to a confidentiality agreement. Dr. Kapoor also controls Inpharmakon Corporation, a party to one of our development agreements. Dr. Kapoor is the trustee of the John N. Kapoor Trust, dated September 30, 1989 which is a partner in Kapoor-Pharma Investments, L.P.

Pierre Lapalme was elected a director in April 2000. His term as director will expire at the annual meeting of the stockholders to be held in 2002. Mr. Lapalme has served as the President and Chief Executive Officer of Ethypharm Inc. (North America), a global drug delivery systems company, since 1997. He is non-executive Chairman of the Board of DiagnoCure Inc., a biopharmaceutical company specializing in the development and marketing of products aimed at the diagnosis and treatment of genito-urinary cancers. He is a director of Ferring Canada Inc., a global pharmaceutical company, and Biovet Inc., a greater-Montreal based veterinary product company. He is a former member of the Board of the National Pharmaceutical Council U.S.A. and of the Pharmaceutical Manufacturers Association of Canada (PMAC). From 1979 to 1990, Mr. Lapalme was Chief Executive Officer and President of Rhone-Poulenc Canada Inc. and Rhone-Poulenc Pharmaceuticals North America. He was appointed Senior Vice President and General Manager Rhone-Poulenc Rorer North America in 1990 and served in that position until 1994. Mr. Lapalme attended the University of Western Ontario and INSEAD France.

Jon S. Saxe was elected a director in January 2000. His term as director will expire at the annual meeting of stockholders to be held in 2004. He also serves as a director of Protein Design Labs, Inc. Mr. Saxe served as President of Protein Design Labs, Inc. from January 1995 to May 1999. In addition, he is a director of Protein Design Labs, Inc., Questcor Pharmaceuticals Inc., Incyte Genomics Inc., ID Biomedical Corporation, Insite Vision, SciClone Pharmaceuti-

cals, Inc. and is Chairman of Point Biomedical Corporation and Iconix Pharmaceuticals. Mr. Saxe served as President of Saxe Associates, a biotechnology consulting firm, from May 1993 to December 1994 and is currently a Principal. He served as the President, Chief Executive Officer and a director of Synergen, Inc., a biopharmaceutical company, from October 1989 to April 1993. Mr. Saxe served in various positions including Vice President of Licensing and Corporate Development and Head of the Patent Law Department for Hoffmann-LaRoche, Inc. from 1960 through 1989. Mr. Saxe received a B.S. Ch.E. degree from Carnegie-Mellon University, a J.D. degree from George Washington University School of Law and an L.L.M. degree from New York University School of Law.

#### SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our executive officers, directors and 10% stockholders to file reports regarding initial ownership and changes in ownership with the Securities and Exchange Commission and the Nasdaq Stock Market. Executive officers, directors and 10% stockholders are required by Securities and Exchange Commission regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of copies of forms filed with the Securities and Exchange Commission pursuant to Section 16(a) of the Exchange Act or written representations from reporting persons, we believe that with respect to 2001, all Section 16(a) filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were complied with other than the following: The Form 4 reporting Brent Dixon's December 2001 sale of 25,000 shares of common stock and gift of 200,000 shares of common stock was filed late and the Form 4 reporting Kapoor-Pharma Investments, L.P.'s December 2001 distribution of shares of common stock to its partners was filed late.

#### ITEM 11. EXECUTIVE COMPENSATION

This information is incorporated by reference from our Proxy Statement for the 2002 Annual Meeting of Stockholders under the heading "Executive Compensation."

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

This information is incorporated by reference from our Proxy Statement for the 2002 Annual Meeting of Stockholders under the heading "Security Ownership of Certain Beneficial Owners and Management."

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

This information is incorporated by reference from our Proxy Statement for the 2002 Annual Meeting of Stockholders under the heading "Certain Relationships and Related Transactions."

## PART IV

## ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

## (a) Documents filed as a part of this report:

(1) Financial Statements	
Report of Independent Public Accountants.....	40
Consolidated Balance Sheets as of December 31, 2000 and 2001.....	41
Consolidated Statements of Operations for the years ended December 31, 1999, 2000 and 2001.....	42
Consolidated Statements of Stockholders' Equity for the years ended December 31, 1999, 2000, and 2001.....	43
Consolidated Statements of Cash Flows for the years ended December 31, 1999, 2000, and 2001.....	44
Notes to Consolidated Financial Statements.....	45
(2) Financial Statement Schedule	
Report of Independent Public Accountants.....	63
Valuation and Qualifying Accounts..... All other schedules have been omitted because of the absence of conditions under which they are required or because the required information is given in the above-listed financial statements or notes thereto	64

(3) The following Exhibits are filed herewith or incorporated herein by reference.

EXHIBIT NUMBER	DESCRIPTION
-----	-----
*3.1	-- Restated Certificate of Incorporation of the Registrant
*3.2	-- Amended and Restated Bylaws of the Registrant
*4.1	-- Form of Stock Certificate
*****4.2	-- Credit Agreement dated as of March 5, 2002 among the Registrant, Various Lenders, Bank of America, N.A. as Syndicate Agent, LaSalle Bank National Association as Documentation Agent and Bankers Trust Company, as Administrative Agent
*4.6	-- Reimbursement Agreement dated April 14, 2000 between the Registrant and Kapoor Children's 1992 Trust
*10.1	-- 1997 Non-Qualified Stock Option Plan
*10.2	-- 2000 Stock Plan
*10.3	-- Form of Nonqualified Stock Option Agreement
*10.4	-- Form of Employment Agreement dated as of January 1, 2000 between the Registrant and Certain of its Executive Officers
***10.5	-- Form of Employment Agreement dated as of January 21, 2002 between the Registrant and its Executive Officers.
**10.6	-- Amendment to Employment Agreement dated January 22, 2001 between the Registrant and its Executive Officers

EXHIBIT NUMBER	DESCRIPTION
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*10.7	-- Convertible Term Loan Note dated January 11, 1999 made by the Registrant for the Benefit of Kapoor Pharma Investments, L.P., as Amended by Amendment No. 1 to the Convertible Term Note dated January 11, 1999 made by the Registrant for the Benefit of Kapoor Pharma Investments, L.P.
*10.8	-- Convertible Term Note Agreement dated January 11, 1999 between the Registrant and Kapoor Pharma Investments, L.P., as Amended by Amendment No. 1 to the Convertible Term Note dated January 11, 1999 made by the Registrant for the Benefit of Kapoor Pharma Investments, L.P.
*10.9	-- Lease Agreement Dated June 28, 1998 between the Registrant and Asc North Fulton Associates Joint Venture
***10.10	-- Lease Agreement dated December 31, 2001 between the Registrant and Castle Investment Company, Inc.
*+10.11	-- Development and Supply Agreement dated March 25, 1999 between the Registrant and Penwest Pharmaceuticals Co.
*+10.12	-- Collaboration Agreement dated October 31, 1998 between the Registrant and Inpharmakon Corporation
*+10.13	-- Exclusive Patent License Agreement dated January 1, 2000 between the Registrant and Jame Fine Chemicals, Inc.
*+10.14	-- Exclusive Distribution Agreement dated January 1, 1996 between the Registrant and Unisource, Inc.
*+10.15	-- Manufacturing and Supply Agreement dated April 23, 1999 between the Registrant and Mikart, Inc.
*+10.16	-- Product Supply Agreement dated January 29, 1999 between the Registrant and American Home Products Corporation
*+10.17	-- License Agreement dated January 29, 1999 between the Registrant and American Home Products Corporation
*+10.18	-- Distribution Agreement dated July 22, 1999 between the Registrant and G. Pohl-Boskamp GmbH & Co.
*10.19	-- Form of Indemnity Agreement between the Registrant and its Directors and Executive Officers
*+10.20	-- Asset Purchase Agreement dated April 10, 2000 between the Registrant and Warner-Lambert Company
*+10.21	-- Supply Agreement dated April 14, 2000 between the Registrant and Warner-Lambert Company
*+10.22	-- Asset Purchase Agreement dated April 14, 2000 between the Registrant and Warner-Lambert Company
*10.23	-- Amendment No. 1 to the Product Development and Supply Agreement, dated May 3, 2000 between the Registrant and Penwest Pharmaceuticals Co.
*10.24	-- Amendment to the Collaboration Agreement, dated May 3, 2000 between the Registrant and Inpharmakon Corporation
++10.25	-- Asset Purchase Agreement dated July 27, 2001 between the Registrant and Sanofi-Synthelabo, Inc.
++10.26	-- Supply Agreement dated May 3, 2001 between Sanofi-Synthelabo, Inc. and Banner Pharmacaps Inc.
++10.27	-- Manufacturing and Supply Agreement dated as of October 1, 1999 between Sanofi-Synthelabo, Inc. and Patheon, Inc.

EXHIBIT NUMBER		DESCRIPTION
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+++10.28	--	Manufacturing and Supply Agreement dated January 21, 2001 between the Registrant and Mikart, Inc.
***10.29	--	Mutual Release Agreement dated as of December 19, 2001 between the Registrant and R. Brent Dixon
***10.30	--	Letter of Separation of Employment dated December 18, 2001 between the Registrant and R. Brent Dixon
+++10.31	--	Asset Purchase Agreement by and between the Registrant and Dura Pharmaceuticals, Inc. dated as of December 21, 2001
++++10.32	--	Supply Agreement between the Registrant and Dura Pharmaceuticals, Inc. dated December 21, 2001
*****10.33	--	Asset Purchase Agreement between the Registrant and AstraZeneca UK Limited dated February 12, 2002
*****10.34	--	Distributorship Agreement between the Registrant and Bayer AG dated December 12, 2001
***10.35	--	Trademark Purchase and Assignment Agreement by and between the Registrant and Bayer Aktiengellschaft dated as of December 13, 2001
***10.36	--	First Amendment to Asset Purchase Agreement dated January 17, 2002 between the Registrant and Sanofi-Synthelabo, Inc.
*****10.34	--	Distributorship Agreement between the Registrant and Bayer AG dated December 12, 2001
***10.35	--	Trademark Purchase and Assignment Agreement by and between the Registrant and Bayer Aktiengellschaft dated as of December 13, 2001
***10.36	--	First Amendment to Asset Purchase Agreement dated January 17, 2002 between the Registrant and Sanofi-Synthelabo Inc.
*****10.37	--	Exclusive Distribution Agreement effective as of December 18, 1998 between the Registrant and Unisource, Inc.
21	--	Subsidiary of the Registrant
23	--	Consent of Arthur Andersen LLP
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* Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-30764).		
** Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-56954).		
*** Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-83698).		
***** Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-83698). The Registrant has requested confidential treatment for certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended.		
+ Confidential treatment was granted for certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended.		
++ Incorporated by reference from the Registrant's Form 10-Q for the quarter ended September 30, 2001 (Commission File No. 000-30123). The Company has requested confidential treatment of portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.		
+++ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on December 13, 2001 (Commission File No. 000-30123). The Registrant has requested confidential treatment of portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.		
++++ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 7, 2001 (Commission File No. 000-30123). The Registrant has requested confidential treatment of portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.		
***** Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 20, 2002 (Commission File No. 000-30123). The Registrant has requested confidential treatment of portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.		

## (b) Reports on Form 8-K.

On December 13, 2001, we filed a Form 8-K pursuant to Item 5 to report that we had entered into a manufacturing and supply agreement for our Robinul products. No financial statements were filed with this report.

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## SIGNATURES

In accordance with the requirements Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FIRST HORIZON PHARMACEUTICAL  
CORPORATION

March 26, 2002

By: /s/ MAHENDRA G. SHAH, PH.D.

-----  
Mahendra G. Shah, Ph.D.  
Chairman of the Board, Chief  
Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and the dates indicated:

SIGNATURE	TITLE	DATE
/s/ MAHENDRA G. SHAH, PH.D. ----- Mahendra G. Shah, Ph.D.	Chairman of the Board, Chief Executive Officer and President (principal executive officer)	March 26, 2002
/s/ JOHN N. KAPOOR, PH.D. ----- John N. Kapoor, Ph.D.	Director	March 26, 2002
/s/ BALAJI VENKATARAMAN ----- Balaji Venkataraman	Executive Vice President, Chief Financial Officer, Chief Operating Officer and Secretary (principal financial and accounting officer)	March 26, 2002
----- Jon S. Saxe	Director	
/s/ PIERRE LAPALME ----- Pierre Lapalme	Director	March 26, 2002
/s/ JERRY N. ELLIS ----- Jerry N. Ellis	Director	March 26, 2002

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REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders of  
First Horizon Pharmaceutical Corporation

We have audited the accompanying consolidated balance sheets of FIRST HORIZON PHARMACEUTICAL CORPORATION (a Delaware corporation) and subsidiary as of December 31, 2000 and 2001 and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of First Horizon Pharmaceutical Corporation and subsidiary as of December 31, 2000 and 2001 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Atlanta, Georgia  
February 12, 2002

## FIRST HORIZON PHARMACEUTICAL CORPORATION

CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT SHARE DATA)

	DECEMBER 31,	
	2000	2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents.....	\$14,228	\$ 53,458
Accounts receivable, net of allowance for doubtful accounts and discounts of \$284 and \$1,087 at December 31, 2000 and December 31, 2001, respectively.....	6,710	12,244
Inventories.....	2,648	4,363
Samples and other prepaid expenses.....	1,341	1,243
Income taxes receivable.....	--	1,674
Current deferred tax assets.....	1,203	323
Total current assets.....	26,130	73,305
Property and equipment, net.....	803	710
Other assets:		
Intangibles, net.....	23,150	92,849
Deferred tax assets.....	--	2,230
Other.....	--	1,056
Total other assets.....	23,150	96,135
Total assets.....	\$50,083	\$170,150
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Account payable.....	\$ 1,815	\$ 4,540
Accrued expenses.....	8,987	22,102
Current portion of long-term debt.....	221	--
Total current liabilities.....	11,023	26,642
Long-term liabilities:		
Deferred tax liabilities.....	488	--
Other long-term liabilities.....	--	144
Total liabilities.....	11,511	26,786
<b>COMMITMENTS AND CONTINGENCIES (NOTE 11)</b>		
Stockholders' equity:		
Preferred stock, 1,000,000 shares authorized and none outstanding.....	--	--
Common stock, \$0.001 par value; 40,000,000 shares authorized; 12,972,900 and 27,626,002 shares issued and outstanding at December 31, 2000 and December 31, 2001, respectively.....	13	28
Additional paid-in capital.....	37,792	131,560
Deferred compensation.....	(843)	(557)
Retained earnings.....	1,610	12,333
Total stockholders' equity.....	38,572	143,364
Total liabilities and stockholders' equity.....	\$50,083	\$170,150

The accompanying notes are an integral part of these consolidated balance sheets.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	YEAR ENDED DECEMBER 31,		
	1999	2000	2001
Net revenues.....	\$18,625	\$36,650	\$69,290
Operating costs and expenses:			
Cost of revenues.....	3,140	5,436	10,354
Selling, general and administrative expense.....	12,546	24,217	38,689
Depreciation and amortization.....	424	1,091	2,724
Research and development expense.....	860	1,784	1,819
Total operating costs and expenses.....	16,970	32,528	53,586
Operating income.....	1,655	4,122	15,704
Other (expense) income:			
Interest expense.....	(357)	(324)	(4)
Interest income.....	12	348	1,874
Other.....	8	21	4
Total other (expense) income.....	(337)	45	1,874
Income before provision for income taxes.....	1,318	4,167	17,578
Provision for income taxes.....	(548)	(1,660)	(6,855)
Net income.....	\$ 770	\$ 2,507	\$10,723
Net income per common share:	=====	=====	=====
Basic.....	\$ 0.06	\$ 0.15	\$ 0.44
Diluted.....	\$ 0.06	\$ 0.13	\$ 0.41
Weighted average common shares outstanding:			
Basic.....	12,043	16,612	24,474
Diluted.....	13,463	19,106	25,845

The accompanying notes are an integral part of these consolidated statements.

FIRST HORIZON PHARMACEUTICAL CORPORATION  
 CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
 (IN THOUSANDS, EXCEPT SHARE DATA)

	COMMON STOCK	ADDITIONAL PAID-IN CAPITAL	DEFERRED COMPENSATION	ACCUMULATED (DEFICIT) EARNINGS	ACCUMULATED (DEFICIT) EARNINGS	TOTAL
	SHARES	AMOUNT				
BALANCE, December 31, 1998.....	7,981,248	\$ 8	\$ 2,615	\$ --	\$ (1,667)	\$ 956
Conversion of debt to equity.....	558,395	1	1,744	--	--	1,745
Deferred compensation.....	--	--	1,428	(1,284)	--	144
Net income.....	--	--	--	--	770	770
	-----	-----	-----	-----	-----	-----
BALANCE, December 31, 1999.....	8,539,643	9	5,787	(1,284)	(897)	3,615
Stock options exercised.....	54,963	--	79	--	--	79
Net proceeds from the sale of shares.....	4,378,294	4	31,183	--	--	31,187
Tax benefit from nonqualified stock option exercises.....	--	--	415	--	--	415
Deferred compensation.....	--	--	328	441	--	769
Net income.....	--	--	--	--	2,507	2,507
	-----	-----	-----	-----	-----	-----
BALANCE, December 31, 2000.....	12,972,900	13	37,792	(843)	1,610	38,572
Stock options exercised.....	453,628	--	645	--	--	645
Net proceeds from the sale of shares.....	4,604,266	5	83,679	--	--	83,684
Three-for-two common stock split.....	9,015,397	9	(9)	--	--	--
Stock options exercised post stock split.....	573,468	1	335	--	--	336
Employee stock purchase plan.....	6,343	--	109	--	--	109
Tax benefit from nonqualified stock option exercises.....	--	--	8,922	--	--	8,922
Deferred compensation.....	--	--	87	286	--	373
Net income.....	--	--	--	--	10,723	10,723
	-----	---	-----	-----	-----	-----
BALANCE, December 31, 2001.....	27,626,002	\$28	\$131,560	\$ (557)	\$12,333	\$143,364
	=====	==	=====	=====	=====	=====

The accompanying notes are an integral part of these consolidated statements.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)

	YEAR ENDED DECEMBER 31,		
	1999	2000	2001
<b>Cash flows from operating activities:</b>			
Net income.....	\$ 770	\$ 2,507	\$10,723
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization.....	424	1,091	2,724
Non-cash interest expense.....	145	--	--
Deferred income tax benefit.....	(352)	(241)	(1,838)
Non-cash compensation expense.....	144	769	373
Loss on disposal of equipment.....	--	25	--
Reduction in taxes payable - stock option exercises.....	--	415	8,922
Changes in assets and liabilities, net of acquired assets and liabilities:			
Accounts receivable.....	(1,753)	(3,810)	(5,534)
Inventories.....	(396)	(1,942)	(1,813)
Samples and other prepaid expenses.....	(83)	(788)	98
Income taxes receivable.....	--	--	(1,674)
Notes receivable from related party.....	--	30	--
Accounts payable.....	357	1,021	2,725
Accrued expenses and other.....	1,763	4,198	9,341
Net cash provided by operating activities.....	1,019	3,275	24,047
<b>Cash flows from investing activities:</b>			
Purchase of products.....	(4,000)	(16,509)	(69,179)
Purchase of property and equipment.....	(186)	(547)	(191)
Net cash used in investing activities.....	(4,186)	(17,056)	(69,370)
<b>Cash flows from financing activities:</b>			
Proceeds from (payments on) revolving loan agreement, net.....	197	(800)	--
Principal payments on long-term debt.....	(1,235)	(12,177)	(221)
Proceeds from long-term debt.....	4,000	9,500	--
Net proceeds from issuance of common stock.....	--	31,266	84,774
Net cash provided by financing activities.....	2,962	27,789	84,553
Net change in cash and cash equivalents.....	(205)	14,008	39,230
Cash and cash equivalents, beginning of period.....	425	220	14,228
Cash and cash equivalents, end of period.....	\$ 220	\$ 14,228	\$53,458

The accompanying notes are an integral part of these consolidated statements.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**Description of Business.** First Horizon Pharmaceutical Corporation (formerly Horizon Pharmaceutical Corporation, the "Company"), a Delaware corporation, is a specialty pharmaceutical company that markets and sells brand name prescription products to primary care and select specialty physicians in the United States through their nationwide sales and marketing force. In addition, limited sales to European customers are made through local distributors in the region. The Company focuses on the treatment of cardiovascular, obstetrical and gynecological, pediatric and gastroenterological conditions and disorders. The Company's strategy is to acquire or license pharmaceutical products that other companies do not actively market, or that the Company believes have high sales growth potential, are promotion-sensitive and complement the Company's existing products. In addition, the Company seeks to maximize the value of their drugs by developing new patentable formulations, using new delivery methods and seeking regulatory approval for new indications of existing drugs.

**Principles of Consolidation.** The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

**Use of Estimates.** The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

**Revenue Recognition.** Revenues from product sales are recognized upon shipment to customers and are shown net of sales adjustments for discounts, rebates to customers, returns and other adjustments, which are provided in the same period that the related sales are recorded.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements." SAB No. 101 is applicable to public companies and provides guidance on applying accounting principles generally accepted in the United States to revenue recognition issues in financial statements. Management believes the Company's revenue recognition criteria are consistent with the guidance provided by SAB No. 101.

**Cost of Revenues.** Cost of revenues is comprised of purchased product costs, and includes the amortization of intangible assets associated with manufacturing and supply agreements entered into in connection with the purchase of products.

**Royalties.** The Company pays royalties on the sale of certain products. These costs are included in selling, general and administrative expenses in the accompanying statements of operations. Total royalties were \$620,000, \$2.1 million and \$3.4 million for the years ending December 31, 1999, 2000 and 2001, respectively.

**Research and Development.** Research and development expenses consist primarily of costs incurred to develop formulations, engage contract research organizations to conduct clinical studies, test products under development and engage medical and regulatory consultants. The Company expenses all research and development costs as incurred. Research and development costs were \$860,000, \$1.8 million and \$1.8 million for the years ended December 31, 1999, 2000 and 2001, respectively.

**Sales Deductions.** Rebate costs, which are recorded as a reduction of sales, include estimated amounts for volume rebate programs, contractual price reductions with wholesalers

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

and insurance providers, and certain other sales related deductions. Provision for these estimated costs are recorded at the time of sale and are periodically adjusted to reflect actual experiences.

**Product Returns.** The Company's customers generally may return product from six months prior to the expiration date of the product until six months after expiration. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 48, "Revenue Recognition When Right of Return Exists," a provision for these estimated returns is recorded at the time of sale and is periodically adjusted to reflect actual experience. These costs are recorded as a reduction to sales.

**Cash and Cash Equivalents.** The Company considers only those investments that are highly liquid, and readily convertible to cash with an original maturity of three months or less to be cash equivalents.

**Concentration of Credit Risk.** The Company extends credit on an uncollateralized basis primarily to wholesale drug distributors and retail pharmacy chains throughout the United States. Historically, the Company has not experienced significant credit losses on its accounts. The Company's four largest customers accounted for approximately 69% and 82% of accounts receivable at December 31, 2000 and 2001, respectively.

The following table presents a summary of sales to significant customers as a percentage of the Company's total revenues:

CUSTOMER	1999	2000	2001
McKesson Corporation.....	28.2%	28.7%	21.5%
Cardinal Health, Inc. .....	19.4	14.4	21.2
AmerisourceBergen Corporation .....	15.0	18.9	20.3
Bindley Western Industries.....	9.5	10.3	18.9

The mix of sales of the Company's products changes as products are added. On a combined basis, products with sales greater than 10% of the Company's sales comprised approximately 64%, 66%, and 66% of total sales in 1999, 2000 and 2001, respectively.

The Company's international sales represent less than 3% of sales for the periods presented.

**Segment Reporting.** The Company operates in a single segment, the sale and marketing of prescription products.

**Inventories.** Inventories consist of purchased pharmaceutical products and are stated at the lower of cost or market. Cost is determined using the first-in, first-out method, and market is considered to be net realizable value. Inventories consist of finished product and bulk product awaiting processing and packaging into finished product. Inventories at December 31, 2000 and 2001 consisted of (in thousands):

	2000	2001
Bulk product.....	--	581
Finished product.....	2,648	3,782
.....	-----	-----
	2,648	4,363
	=====	=====

**Samples.** Samples primarily consist of product samples used in the sales and marketing efforts of the Company's products. Samples are expensed upon distribution. Sample inventories at December 31, 2000 and 2001 were \$1.1 million and \$827,000, respectively.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

**Property and Equipment.** Property and equipment are recorded at cost, less accumulated depreciation and amortization. Major improvements, which extend the lives of existing property and equipment, are capitalized. Expenditures for maintenance and repairs are charged to expense as incurred. Upon retirement or disposal of assets, the cost and related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is recognized as other income (expense) in the statement of operations.

Depreciation is provided for on the straight-line basis over the estimated useful lives of the assets as follows:

Office equipment.....	five to ten years
Furniture and fixtures.....	five to ten years
Computer hardware and software.....	three to five years
Leasehold improvements.....	based on term of lease

The components of property and equipment at December 31, 2000 and 2001 are as follows (in thousands):

	2000	2001
	-----	-----
Office equipment.....	\$ 87	\$ 93
Furniture and fixtures.....	216	227
Computer hardware and software.....	455	477
Leasehold improvements.....	308	318
	-----	-----
	1,066	1,115
Less accumulated depreciation and amortization.....	(263)	(405)
	-----	-----
Property and equipment, net.....	\$ 803	\$ 710
	=====	=====

Depreciation and amortization expense related to property and equipment for the years ended December 31, 1999, 2000 and 2001 was \$69,000, \$141,000 and \$284,000, respectively.

In the event that facts and circumstances indicate that the carrying amounts of property and equipment may be impaired, an evaluation of recoverability is performed using the estimated future undiscounted cash flows associated with the asset compared to the asset's carrying amount to determine if a write-down is required, pursuant to the provisions of SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" and its related interpretations.

**Intangible Assets.** Intangible assets, which include license rights, trademarks, managed care contracts and distribution, manufacturing and supply agreements, are stated at cost, net of accumulated amortization. These costs are capitalized and amortized on a straight-line basis over the estimated periods benefited by the asset (1 to 20 years). Amortization of such assets, excluding distribution, manufacturing and supply agreements, is included in depreciation and amortization expense in the accompanying statements of operations. Amortization expense for the years ended December 31, 1999, 2000 and 2001 totaled \$355,000, \$950,000 and \$2.6 million, respectively. Included in the \$2.6 million of amortization expense in 2001 is \$118,000 of amortization of the upfront fees paid to secure distribution, manufacturing and supply agreements in connection with two product acquisitions in 2001. This amortization expense of \$118,000 is included in cost of revenues. These distribution, manufacturing and supply agreements are discussed in more detail in Notes 8 and 9.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

In accordance with SFAS No. 121, the Company continually reevaluates the propriety of the carrying amount of intangibles as well as the related amortization period to determine whether current events and circumstances warrant adjustments to the carrying values and/or estimates of useful lives. This evaluation is performed using the estimated projected future undiscounted cash flows associated with the asset compared to the asset's carrying amount to determine if a write-down is required. To the extent such projections indicate that the undiscounted cash flows are not expected to be adequate to recover the carrying amounts, the assets are written down to fair value as determined by discounting future cash flows.

**Shipping and Handling.** Costs incurred related to freight-in are included in cost of revenues and costs related to freight-out are included in selling, general and administrative expense.

**Income Taxes.** The Company provides for income taxes in accordance with SFAS No. 109 "Accounting for Income Taxes." SFAS No. 109 requires recognition of deferred tax assets and liabilities using currently enacted tax rates.

**Advertising Costs.** The Company charges the costs of advertising to expense as incurred. Advertising expenses were \$179,000, \$1.2 million and \$2.9 million for the years ending December 31, 1999, 2000 and 2001, respectively.

**Financial Instruments.** The Company's carrying value of financial instruments approximates fair value due to the short maturity of those instruments.

**Foreign Currency Exposure.** Certain of the Company's product purchases and sales are denominated in foreign currencies. Gains or losses on foreign currency transactions are included in income as incurred. The Company enters into short term forward foreign exchange contracts in relation to certain purchases of one of its products. These forward contracts are not designated as hedging instruments and as such any change in fair value while open is recognized currently in earnings. This gain or loss offsets the transaction gain or loss on the underlying foreign denominated payables. Foreign denominated payables, receivables and open exchange contracts as of December 31, 2001 are insignificant.

**Common Stock Split.** On August 24, 2001 the Company's Board of Directors authorized a three-for-two stock split effected in the form of a stock dividend distributed on September 24, 2001 to stockholders of record as of September 10, 2001. As a result of the stock split, the accompanying consolidated financial statements reflect an increase in the number of outstanding shares of common stock and the transfer of the par value of these additional shares from paid-in capital. All references to the number of shares (other than common stock issued and outstanding on the 2000 Consolidated Balance Sheet and transactions prior to September 10, 2001 on the Consolidated Statements of Stockholders' Equity), per share amounts and any other reference to shares in the Consolidated Financial Statements and the accompanying Notes to the Consolidated Financial Statements have been adjusted to reflect the split on a retroactive basis.

**Earnings Per Share.** As required by SFAS No. 128, "Earnings Per Share," the Company has presented basic and diluted earnings per common share amounts in the accompanying financial statements. Basic earnings per common share are calculated based on the weighted average common shares outstanding during the year. Diluted earnings per common share are calculated similar to basic earnings per common share except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of stock options, if dilutive. The number of additional shares is calculated by assuming that outstanding stock options were exercised and that the proceeds from such exercises were used to acquire shares of common stock at the average market price during the period.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

Below is the calculation of basic and diluted net income per common share (in thousands, except per share data):

	YEAR ENDED DECEMBER 31,		
	1999	2000	2001
Net income.....	\$ 770	\$ 2,507	\$10,723
Weighted average common shares outstanding -- basic.....	12,043	16,612	24,474
Dilutive effect of stock options.....	1,420	2,494	1,371
Weighted average common shares outstanding -- diluted.....	13,463	19,106	25,845
Basic net income per share.....	\$ 0.06	\$ 0.15	\$ 0.44
Diluted net income per share.....	\$ 0.06	\$ 0.13	\$ 0.41

The number of outstanding options which are excluded from the above calculation as their impact would be anti-dilutive are 0, 122,850 and 692,650 for the years ended December 31, 1999, 2000 and 2001, respectively.

**Reclassifications.** Certain prior year amounts have been reclassified to conform with the current year financial statement presentation.

**Supplemental Cash Flow Disclosures.** Supplemental cash flow information at December 31, 1999, 2000 and 2001 is as follows (in thousands):

	1999	2000	2001
Cash paid for taxes.....	\$778	\$940	\$2,163
Cash paid for interest.....	\$236	\$385	\$ 7

**New Accounting Pronouncements**

In July 2001, the FASB issued SFAS No. 141, "Business Combinations." SFAS No. 141 eliminates the pooling-of-interest method of accounting for business combinations. SFAS No. 141 is effective for any business combination completed after June 30, 2001. The Company does not expect the application of the provisions of SFAS No. 141 will have a material impact on its financial position or results of operations.

In July 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets." Under SFAS No. 142, goodwill and indefinite lived intangible assets are no longer amortized. Separate intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives. SFAS No. 142 also establishes a new method of testing goodwill and other unamortized intangible assets for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that would reduce the fair value of that goodwill or other intangible asset below its carrying value. The amortization provisions of SFAS No. 142 apply to goodwill and other intangible assets acquired after June 30, 2001. The Company does not expect the application of the provisions of SFAS No. 142 will have a material impact on its financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets." SFAS No. 144 addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and is effective for financial periods after January 1, 2002. The Company does not expect the application of the provisions of SFAS No. 144 will have a material impact on its financial condition or results of operations.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

## 2. REVOLVING LOAN AGREEMENT

In May 1998, the Company entered into a revolving loan agreement with a bank under which the Company could borrow up to \$1.0 million, subject to borrowing base limitations based on eligible accounts receivable and inventory balances, as defined in the agreement. Borrowings under the revolving loan agreement bore an interest rate of the bank's prime rate and were secured by the Company's assets. The revolving loan agreement was amended and restated on December 22, 1998 to provide for partial financing of a product acquisition through a term loan. Under the amended agreement, terms of the revolving loan facility provided for up to \$2.5 million, subject to borrowing base limitations based on eligible accounts receivable and inventory, as defined in the agreement. In January 2000, the loan agreement was amended and restated to provide for borrowings up to \$3.5 million through June 30, 2000, reverting back to \$2.5 million from June 30, 2000 to January 31, 2001. In April 2000, the Company further amended its credit facility to include up to \$13.0 million of bridge financing to finance acquisitions, and to extend the term of the revolving loan facility to May 2, 2001. On April 14, 2000, the Company borrowed \$9.5 million under the bridge loan for the acquisition of Ponstel. Borrowings under the bridge loan bore an interest rate of the Company's choice of the bank's prime rate or LIBOR plus 1.5%. The bridge loan matured, and was repaid, upon the completion of the Company's initial public offering on May 31, 2000. The weighted average outstanding balance under the revolving loan agreement for the year ended December 31, 2000 was \$1.9 million. As of December 31, 2000 and 2001 there were no borrowings against the revolving loan. The interest rate at December 31, 2000 and 2001 was 9.0% and 4.8%, respectively, and the Company had availability under the terms of the agreement of \$2.5 million, and was subject to a 0.25% fee on the unused portion. In May 2001, the term of the revolving loan facility was extended to May 31, 2002. The revolving loan agreement contains certain restrictive covenants including, among other things, minimum EBITDA levels and a debt to equity ratio. The revolving loan agreement is to be terminated as a condition of and in connection with the credit facility expected to be entered into in 2002 with a syndicate arranged by Deutsche Bank Alex. Brown, Inc. This facility is discussed in more detail in Note 14.

## 3. LONG-TERM DEBT

Long-term debt as of December 31, 2000 consisted of a note payable to the seller in a product acquisition of \$221,000, which was repaid during 2001.

## 4. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	2000	2001
	-----	-----
Employee compensation and benefits.....	\$1,549	\$ 3,325
Product returns.....	825	3,374
Sales deductions.....	1,814	5,637
Accrued royalties.....	580	1,042
Assumed liabilities -- product acquisitions.....	2,027	5,593
Income taxes payable.....	736	--
Other.....	1,456	3,131
	-----	-----
	\$8,987	\$22,102
	=====	=====

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

## 5. STOCKHOLDERS' EQUITY

In December 1999, the Company issued 837,593 shares of common stock to the Company's majority stockholder upon the conversion of \$1.6 million of convertible debt incurred in January 1999 for the purchase of a product license and accrued interest of \$145,000 thereon to common stock. The shares were converted at a rate of \$2.083 as stipulated in the applicable agreement. The original debt agreement stipulated an interest rate of prime plus 2.0% (10.25% at the conversion date).

In May 2000, the Company completed its initial public offering and issued 5,700,000 shares of common stock at a price of \$5.33 per share. In June 2000, the Company's underwriters exercised their over-allotment option and an additional 855,000 shares of common stock were issued at a price of \$5.33 per share. These offerings generated proceeds, net of offering expenses, of \$31.1 million, which the Company used to repay debt, finance product acquisitions, and for general corporate purposes.

During 2000, the Company issued 12,441 shares of common stock under its employee stock purchase plan.

In December 2000, the Company entered into a separation agreement with a retiring executive, whereby the executive will receive severance and other benefits. In addition, the vesting portion of his stock options was accelerated, generating compensation expense of \$361,000.

In May 2001, the Company completed a follow-on offering of 6,900,000 shares of common stock at a price of \$12.87 per share. The Company received net proceeds of \$83.6 million from the offering after deducting offering expenses. The proceeds will be used to finance product acquisitions and for general corporate purposes.

During 2001, the Company issued 12,742 shares of common stock under its employee stock purchase plan.

Under the Company's Restated Certificate of Incorporation the Board of Directors has the authority, without further action by the stockholders, to issue up to 1,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by the stockholders. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the Company, which could have a depressive effect on the market price of our common stock. The Company has no present plan to issue any shares of preferred stock. As of December 31, 2000 and December 31, 2001 there were no shares of preferred stock outstanding.

## 6. STOCK OPTIONS

Pursuant to the Company's 1997 Non-Qualified Stock Option Plan (the "1997 Plan"), the Board of Directors approved the issuance of options to purchase shares of common stock of the Company to various employees. Under the plan, 6,000,000 shares of common stock were reserved for issuance. Vesting periods range from immediate to four years, and options granted generally expire seven years from the date of grant. All options also include accelerated vesting

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

provisions in the event of a change in control, as defined in the plan. In 2000, the Company terminated the 1997 Plan and no additional grants of stock options will be made under the 1997 Plan. At December 31, 2001, 1,228,280 options remained issued and outstanding under the 1997 Plan.

On February 14, 2000, the Board of Directors and stockholders approved the 2000 Stock Plan (the "2000 Plan"). This plan provides for the granting of incentive stock options, nonqualified stock options, stock awards or stock bonuses, and sales of stock. The 2000 Plan provides for the grants of these options and other awards to officers, directors, full- and part-time employees, advisors and consultants. Only full-time employees may receive incentive stock options. The Company has reserved 3,000,000 shares of common stock for issuance under the 2000 Plan. The Company's compensation committee administers the 2000 Plan and has the sole authority to determine the meaning and application of the terms of the plan and all grant agreements, the persons to whom option or stock grants are made, the nature and amount of option or stock grants, the price to be paid upon exercise of each option, the period within which options may be exercised, the restrictions on stock awards, and the other terms and conditions of awards. All options granted under the 2000 Plan include accelerated vesting provisions in the event of a change in control, as defined in the plan. The 2000 Plan will terminate in February 2010. At December 31, 2001, 1,755,796 options were issued and outstanding and 1,188,320 options were available for issue under the 2000 Plan.

The Company has granted stock options to officers, directors, and employees as follows:

	NUMBER OF SHARES SUBJECT TO OPTION	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding at December 31, 1998.....	1,458,000	\$ 0.48
Granted.....	1,178,250	1.66
Canceled.....	(7,500)	1.50
=====	=====	=====
Outstanding at December 31, 1999.....	2,628,750	1.00
Granted.....	579,600	7.26
Canceled.....	(78,900)	4.98
Exercised.....	(82,444)	0.96
=====	=====	=====
Outstanding at December 31, 2000.....	3,047,006	2.09
Granted.....	1,505,674	19.36
Canceled.....	(314,694)	7.53
Exercised.....	(1,253,910)	0.79
=====	=====	=====
Outstanding at December 31, 2001.....	2,984,076	\$10.78
=====	=====	=====

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The following table sets forth the range of exercise prices, number of shares, weighted average exercise price, and remaining contractual lives by similar price and grant date at December 31, 2001.

RANGE OF EXERCISE PRICE	OUTSTANDING			EXERCISABLE	
	OUTSTANDING AT DECEMBER 31, 2001	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	EXERCISABLE AT DECEMBER 31, 2001	WEIGHTED AVERAGE EXERCISE PRICE
	-----	-----	-----	-----	-----
\$ 0.33 -- \$ 1.77	1,189,750	4.33 years	\$ 1.45	705,250	\$ 1.31
5.33 -- 7.13	304,955	5.22 years	5.79	41,954	5.65
12.00 -- 14.96	591,821	6.04 years	14.48	22,814	12.73
15.17 -- 20.00	211,950	6.24 years	17.27	186	17.15
20.28 -- 29.22	685,600	6.81 years	24.00	--	N/A
Total	2,984,076	=====		770,204	=====

Upon the exercise of options, the Company became entitled to a tax effected benefit of \$415,000 and \$8.9 million in 2000 and 2001, respectively, which is equal to the number of options multiplied by the difference between the market price of the options as of the date of exercise and the exercise price for the options, adjusted for the impact of tax rates. The impact of the benefit has been credited to additional paid-in capital.

The Company applies Accounting Principles Board Opinion 25 and related interpretations in accounting for its stock options issued to employees. Accordingly, the Company records compensation expense for any stock option grants with exercise prices lower than fair value, recognized ratably over the vesting period. The Company has recognized compensation expense related to stock option grants of \$144,000, \$769,000 and \$373,000 in 1999, 2000 and 2001, respectively. The 2000 compensation expense includes \$361,000 related to accelerated vesting granted to a retiring executive.

All option grants during 1999 were granted with exercise prices below the fair market value at the date of grant. These options had a grant date weighted average fair value of \$2.75. All options granted in 2000 and 2001 have been granted at exercise prices equal to fair market value at the date of grant.

Had compensation costs for the Company's options been determined using option-pricing models prescribed by SFAS No. 123, "Accounting for Stock Based Compensation," the Company's pro forma net income per common share would have been reported as follows (in thousands, except per share amounts):

	1999	2000	2001
Net income:	-----	-----	-----
As reported	\$ 770	\$2,507	\$10,723
Pro forma	477	2,260	9,774
Net income per common share -- basic:			
As reported	0.06	0.15	0.44
Pro forma	0.04	0.14	0.40
Net income per common share -- diluted:			
As reported	0.06	0.13	0.41
Pro forma	0.04	0.12	0.38

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The weighted average value of options granted during 1999, 2000 and 2001 is estimated at \$2.01, \$4.88 and \$11.98 per share, respectively. The value of options is estimated on the date of the grant using the following weighted average assumptions:

	1999	2000	2001
Risk-free interest rate.....	5.57%	6.45%	4.10%
Expected dividend yield.....	--	--	--
Expected lives.....	4 years	4 years	4 years
Expected volatility.....	--%	42.0%	59.0%

The Company adopted an employee stock purchase plan on February 14, 2000 that is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code. The Company has reserved 750,000 shares of common stock for the stock purchase plan. In order to participate in the stock purchase plan, employees must meet eligibility requirements, including length of employment. Participating employees will be able to direct the Company to make payroll deductions of up to 7.0% of their compensation during an offering period for the purchase of shares of the Company's common stock. Each offering period will be six months. The stock purchase plan will provide participating employees with the right, subject to specific limitations, to purchase the Company's common stock at a price equal to 85.0% of the lesser of the fair market value of the Company's common stock on the first or last day of the offering period. The Board of Directors has the authority to amend, suspend or discontinue the stock purchase plan as long as the change will not adversely affect participants without their consent and as long as the Company receives the stockholder approval required by law. The stock purchase plan will terminate on December 31, 2010.

## 7. INCOME TAXES

The income tax provision (benefit) for 1999, 2000 and 2001 consisted of the following (in thousands):

	1999	2000	2001
Current.....	\$ 900	\$ 2,021	\$ 8,693
Deferred.....	(352)	(361)	(1,838)
	-----	-----	-----
	\$ 548	\$ 1,660	\$ 6,855
	=====	=====	=====

A reconciliation of the statutory rate to the effective rate as recognized in the statements of operations is as follows:

	1999	2000	2001
Federal statutory rate.....	34.0%	34.0%	34.0%
State income tax, net of federal benefit.....	5.0	3.8	3.9
Non-deductible expenses and other.....	2.6	2.0	1.1
	-----	-----	-----
	41.6%	39.8%	39.0%
	=====	=====	=====

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

Deferred tax assets and liabilities reflect the impact of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts recognized for income tax purposes. Significant components of the Company's net deferred tax assets as of December 31, 2000 and 2001 are as follows (in thousands):

	2000	2001
Deferred tax assets:	-----	-----
Accrued returns.....	\$1,027	\$1,299
Accrued liabilities and reserves.....	110	675
Deferred compensation.....	411	542
Accrued commission.....	71	377
Other assets.....	20	50
	-----	-----
	\$1,639	\$2,943
	=====	=====
Deferred tax liabilities:	-----	-----
Intangibles.....	\$ 870	\$ 356
Other liabilities.....	54	34
	-----	-----
	924	390
	-----	-----
Net deferred tax assets.....	\$ 715	\$2,553
	=====	=====

## 8. ACQUISITIONS/INTANGIBLE ASSETS

On January 29, 1999, the Company acquired exclusive rights in the United States to Robinul and Robinul Forte tablets from American Home Products Corporation ("AHP") for \$4.0 million in cash with an additional \$1.8 million financed by the seller. Pursuant to the acquisition, the Company also assumed liabilities of \$193,000 for returns of products shipped by the seller prior to the acquisition date. The Company has recorded the total purchase price for this acquisition including the liabilities assumed to the licensing rights within intangible assets in its financial statements. The licensing rights are being amortized over an estimated economic life of 20 years. The Company agreed to pay royalties on net sales as long as the Company sells the product.

On April 14, 2000, the Company acquired exclusive rights from Warner-Lambert Company to distribute, market, and sell the drug Ponstel in the United States for \$9.5 million in cash and a \$3.5 million promissory note to the seller. The Company also assumed liabilities of \$1.1 million for certain returns of products shipped by the seller prior to the acquisition date, and returned after October 20, 2000. The Company financed \$9.5 million of the transaction under the bridge loan agreement described in Note 2. The acquisition agreement includes the purchase of the license rights and certain trademarks. The value allocated to tradename and license rights is being amortized over their estimated useful lives of 20 years. In addition, the Company agreed to purchase the entire outstanding inventory of Ponstel for approximately \$100,000. The promissory note was paid in full upon the receipt of proceeds from the Company's initial public offering in June 2000.

On June 22, 2000, the Company acquired exclusive rights from Warner-Lambert Company to market, distribute and sell the drug Cognex and a new unapproved version of Cognex called Cognex CR, in the U.S. and other countries for \$3.5 million in cash. The Company must also pay up to \$1.5 million in additional purchase price if the Company obtains FDA approval to market Cognex CR. The Company also assumed liabilities of \$799,000 for returns of products shipped by Warner-Lambert prior to the acquisition date, and returned after June 22, 2001. The

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

purchase price was allocated among the fair values of intangible assets (primarily tradename and licensing rights) and liabilities assumed and is being amortized over 20 years.

On August 20, 2001, the Company acquired from Sanofi-Synthelabo Inc. ("Sanofi") the Prenate line of prescription prenatal vitamins (the "Prenate Acquisition"), which it believes will complement its obstetrical/gynecological line of products, including Ponstel. The purchase price was \$51.9 million in cash and the assumption of liabilities of \$0.9 million for returns of product shipped by Sanofi prior to the acquisition date, and returned after February 20, 2002 and for estimated contractual price reductions with wholesalers and insurance providers. The agreement includes the purchase of the Prenate license rights, certain tradenames and managed care contracts and a supply agreement. The purchase price was allocated among the fair values of the intangible assets acquired and the liabilities assumed and is being amortized over a period of three to twenty years. The managed care contracts are being amortized over a period of five years and the supply agreement is being amortized over a period of three years. All other intangibles are being amortized over twenty years. The weighted average amortization period is seventeen years. In addition, the Company purchased the outstanding inventory of Prenate for approximately \$50,000. The results of the Prenate line are included in the consolidated statements of operations from August 20, 2001 to December 31, 2001. The preliminary purchase price allocation as of December 31, 2001 is as follows (in thousands):

License rights.....	\$44,926
Tradenames.....	5,500
Managed care contracts.....	1,430
Supply agreement.....	940
	-----
Total.....	52,796
Accumulated amortization.....	(1,151)
	-----
Intangibles, net.....	\$51,645
	=====

For the year ended December 31, 2001, aggregate amortization expense related to the Prenate Acquisition was \$1.2 million related to the period from the purchase date to year-end.

On December 21, 2001, the Company acquired from Dura Pharmaceuticals Inc., an affiliate of Elan Pharmaceuticals PLC ("Elan"), the U.S. rights to Furadantin, a prescription drug used for the treatment of urinary tract infections in children, which the Company believes will complement its pediatric line of products, which includes Tanafed and Tanafed DM, for approximately \$16 million in cash plus the assumption of liabilities of \$324,000 for the return of product shipped by Elan prior to the acquisition date returned after December 31, 2002. The purchase price was allocated among the fair value of the intangible assets acquired and liabilities assumed and is being amortized over a weighted average amortization period of seventeen years. The purchase agreement includes all assets related to Furadantin, including the NDA and the trademark. The license rights and tradename are being amortized over 20 years. Additionally, the Company purchased the outstanding inventory of Furadantin for \$252,000. The Company has also entered into a transitional supply agreement with Elan Pharmaceuticals whereby they will supply the Company with Furadantin until May 2003. The supply agreement

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

is being amortized over its useful life of 17 months. The preliminary purchase price allocation is as follows (in thousands):

License rights.....	\$ 15,804
Tradename.....	320
Supply agreement.....	200
	=====
Total.....	16,324
Accumulated amortization.....	(29)
	=====
Intangibles, net.....	\$16,295
	=====

For the year ended December 31, 2001, aggregate amortization expense related to the Furadantin acquisition was \$29,000 related to the 11 days from the purchase date to year-end.

The unaudited pro forma summary below presents certain financial information as if the Prenate and Furadantin acquisitions had occurred as of January 1, 2000. These pro forma results have been prepared for comparative purposes and do not purport to be indicative of what would have occurred had the acquisitions been made on the first day of the respective years of acquisition. Additionally, these pro forma results are not indicative of future results (in thousands, except per share data):

	FOR THE YEAR ENDED	
	2000	2001
Net revenues.....	\$ 58,298	\$ 84,645
	=====	=====
Net income.....	\$ 4,007	\$ 11,743
	=====	=====
Diluted net income per share.....	\$ 0.21	\$ 0.45
	=====	=====

The purchase price allocations of Prenate and Furadantin are preliminary and subject to revision, with any such revision to be finalized upon the ultimate resolution of the value of certain liabilities assumed, yet no later than the one year anniversary of the purchase date. The Company does not expect any such revisions will have a material impact on the Company's financial position or results of operations.

The purchase prices paid for Prenate and Furadantin were determined based on numerous considerations including a return on investment analysis as well as the impact of competing buyers.

## 9. LICENSE AGREEMENTS AND PRODUCT RIGHTS

On January 1, 1996, the Company obtained exclusive distribution rights from Unisource, Inc. for Tanafed in North America through December 31, 2003 with an option for an additional seven years. The agreement requires the Company to purchase all of their requirements for Tanafed from Unisource, including at least certain minimum quantities of Tanafed in each year of the agreement. In December 1998, the Company obtained exclusive distribution and supply rights from Unisource, Inc. for Tanafed DM in North America through December 2005, subject to an automatic seven year renewal. The agreement requires the Company to purchase all of its requirements for Tanafed DM from Unisource, subject to certain minimum purchase requirements. The Company entered into a patent and license agreement with Jame Fine Chemicals, Inc., the raw materials supplier for Tanafed in January 2000. The agreement grants the Company a semi-exclusive license to use, sell and distribute finished products containing an active ingredient used in Tanafed. Pursuant to the agreement, the Company must pay a royalty

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

on sales of Tanafed. The license continues through the life of the licensed patent, which expires in 2014.

On October 31, 1998, the Company entered into an agreement with Inpharmakon Corporation in which the Company acquired rights to the proprietary information for a migraine product for which the Company plans to conduct clinical studies and submit a new drug application. The agreement expires on October 31, 2008, but the Company may renew it indefinitely after expiration. If the Company does not obtain regulatory approval of the drug within a specified time after filing for such approval and thereafter commence and continue to aggressively market and sell the product, Inpharmakon may terminate the agreement. In the event that Inpharmakon terminates the agreement for failure to achieve these milestones, Inpharmakon may purchase rights to develop the drug. The Company must also pay up to an aggregate of \$950,000 in non-refundable fees to Inpharmakon at various developmental milestones through and including regulatory approval of the product, and, in the event of commercial sales of the product, the Company must pay royalties at rates which management believes are within industry customary ranges. If the Company elects to sell the business opportunity to a third party, the Company must share the proceeds of the sale with Inpharmakon. On May 3, 2000, the Company amended the terms of the agreement with Inpharmakon. Under the amended terms, the Company paid Inpharmakon \$200,000 on June 15, 2000. In addition, a \$200,000 milestone payment was paid to Inpharmakon in December 2001.

In January 1999, the Company acquired exclusive rights in the United States to Robinul and Robinul Forte tablets from American Home Products Corporation. The Company must pay royalties on net sales under its license agreement with American Home Products. The Company entered agreements with Mikart, dated April 23, 1999 and January 21, 2001, for Mikart to become qualified under applicable regulations to manufacture and supply the Company's requirements for Robinul. Mikart became qualified by the FDA to manufacture Robinul on December 3, 2001 and began supplying the Robinul products to the Company in December 2001. Under these agreements, Mikart will manufacture the products for five years from the time Mikart became a qualified manufacturer plus renewal terms of one year until either party elects not to renew. The agreement with Mikart requires that the Company purchase certain designated minimum quantities.

In January 2002, the Company entered into a license agreement with Wyeth-Ayerst Canada Inc. and Whitehall-Robins Inc. under which the Company acquired rights to have the product manufactured, and to market and sell Robinul and Robinul Forte in Canada. The Company will pay Wyeth-Ayerst Canada a royalty on net sales of Robinul in Canada.

On March 25, 1999, the Company acquired the rights from Penwest Pharmaceuticals Co. to the application of Penwest's controlled release TIMERx technology to the active ingredient in the migraine product. Under the Penwest agreement, the Company has the right to manufacture, use and sell the developed product in North America and Mexico for a period extending fifteen years from the date a new drug application is issued for the product, as well as a license to the TIMERx(R) patents for such purpose. The Company must pay Penwest an aggregate of up to approximately \$2.6 million of non-refundable fees upon achieving specified development milestones through the first anniversary of the first commercial sale of the product following regulatory approval and royalties upon any sales of the migraine product. To date, the Company has paid Penwest \$427,000, which is included in research and development expense in the accompanying statements of operations. Penwest may terminate the agreement in the event the

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

Company fails to timely achieve designated performance milestones within prescribed time periods.

In July 1999, the Company entered into an agreement with Pohl-Boskamp for the exclusive rights to distribute, market and sell Nitrolingual Pumpspray beginning on February 1, 2000 in the United States for five years plus an additional five year renewal period subject to establishing mutually acceptable minimum purchase requirements. Under the agreement, Pohl-Boskamp supplies the Company with their requirements of product at prices that decrease as volume purchased in each year increases. The Company must purchase designated minimum quantities in each year of the agreement and pay a royalty on net sales of the product. Aventis had exclusive rights through January 2000 to a version of the product containing CFC named Nitrolingual spray. To promote earlier adoption of Nitrolingual Pumpspray, the Company obtained exclusive rights from Aventis to market this CFC product in the United States as of November 22, 1999.

In April 2000, the Company acquired exclusive rights from Pfizer to market, distribute and sell Ponstel in the United States. The total purchase price was \$13.0 million. In April 2000, the Company also entered into a supply agreement with Pfizer under which Pfizer was to supply us with designated quantities of Ponstel through the expiration of the supply agreement, which occurred on March 31, 2001. Pfizer only delivered a portion of the quantity of Ponstel required by the supply agreement during its term. Pfizer has continued to supply Ponstel to us under the same terms. The Company pays Pfizer an agreed upon price for the supply of Ponstel.

In December 2000, the Company signed an agreement with West-ward Pharmaceuticals to manufacture Ponstel after West-ward obtains FDA approval to manufacture the product. The Company anticipates that this will occur by the fourth quarter of 2002. This agreement expires in April 2005 subject to automatic annual renewals. The Company must purchase all of its requirements for Ponstel from West-ward and is subject to minimum purchase requirements. The Company must pay West-ward a price for Ponstel based on a multiple of West-ward's direct cost of goods sold in the manufacture and supply of the product. In addition, the Company must pay West-ward milestone payments, as long as no generics have been introduced, upon certain anniversary dates of FDA approval of the manufacture of Ponstel by West-ward. West-ward is currently in the process of manufacturing the required pilot batches in order to obtain such approval.

For the Cognex product, the Company negotiated a supply agreement with a Warner-Lambert affiliate to continue to manufacture and supply Cognex and the active ingredient in Cognex for two years subject to a one-year renewal. The Company will pay Warner-Lambert's affiliate a production fee for its manufacture of Cognex and the active ingredient. The supply agreement contains designated quantities of Cognex and its active ingredient that Warner-Lambert's affiliate will supply and that the Company must purchase.

In addition, the Company entered into a transition services agreement with Warner-Lambert under which Warner-Lambert provided transitional administrative services to the Company until December 31, 2000 in connection with the sale of Cognex in European countries.

For the Prenate product line, under the terms of the asset purchase agreement, the Company was assigned a contract between Sanofi and Patheon Inc. to manufacture the product line. The term of the agreement is for five years from October 1, 1999 subject to automatic one-year renewals. The Company also assumed a supply and packaging agreement with Banner Pharmacaps Inc. ("Banner") and Sanofi for the supply and packaging of the products. The agreement with Banner is for a term of five years subject to two-year renewals. Under the

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

terms of the supply agreement with Banner, the Company will pay Banner a royalty on net sales above a certain amount of net sales. The Sanofi packaging agreement is for a term of three years subject to a three-year renewal.

Each of the Company's third-party manufacturing agreements requires that the Company purchase all of their product requirements from the manufacturers that are a party to those agreements.

The Company uses third-party manufacturers for the production of its products for development and commercial purposes. Given the general under-utilization of resources, the availability of excess capacity for manufacturing in the marketplace, and the lower cost of outsourcing, the Company intends to continue to outsource manufacturing for the near-term.

The Company relies on third-party suppliers to produce its products. The supplier for one product and the suppliers for components of two other products hold patents relating to their respective products. Due to the patent restrictions, the supply of these three products, whose sales comprised 50.1% of the Company's sales in 2001 are exclusively available through these suppliers.

## 10. RETIREMENT PLAN

In 1996, the Company began a qualified defined contribution 401(k) plan, which provides benefits to substantially all employees. The annual contribution, if any, to the trust is at the discretion of the Board of Directors of the Company. Employer contributions to the plan for the years ended December 31, 1999, 2000 and 2001 were \$36,000, \$52,000 and \$184,000, respectively.

## 11. COMMITMENTS AND CONTINGENCIES

The Company leases its current facility under a non-cancelable operating lease that expires in August 2003. The total rent expense was \$212,000, \$199,000 and \$531,000 for the years ended December 31, 1999, 2000, and 2001, respectively. The rent expense for 2001 includes a charge of \$304,000 for the remaining lease obligation under the Company's existing non-cancelable lease. In December 2001, the Company entered into a new lease agreement for a new facility. The move to the new facility is anticipated early in the second quarter. Additionally, in early 2002, the Company expects to incur approximately \$280,000 in leasehold improvement costs related to the new facility.

The Company leases vehicles for certain employees under non-cancelable lease agreements expiring in 2003. The total vehicle lease expense under the lease agreements for the years ended December 31, 1999, 2000 and 2001 was \$434,000, \$1.3 million and \$1.9 million, respectively.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The total minimum future commitments under leases for years succeeding December 31, 2001 is as follows (in thousands):

Period ending December 31,	
2002.....	\$2,022
2003.....	1,294
2004.....	626
2005.....	626
2006.....	646
Thereafter.....	1,580
	=====
Total.....	\$6,794
	=====

The Company has employment contracts with certain executives, which provide for certain levels of severance in the event of termination without cause or for certain change of control events, as defined.

The Company is involved with various routine legal proceedings incident to the ordinary course of business. None of these proceedings are expected to have a material adverse effect on the consolidated financial statements.

## 12. RELATED-PARTY TRANSACTIONS

The Company purchases repackaging services from Diversified Healthcare Services, a related party. For the years ended December 31, 1999, 2000 and 2001, the amounts paid for repackaging were approximately \$282,000, \$136,000 and \$5,000, respectively.

The Company pays royalties to a related party for particular products sold. For the years ended December 31, 1999, 2000, and 2001, the amounts paid for royalties were approximately \$163,000, \$213,000 and \$40,000, respectively.

The Chairman and Chief Executive Officer of the Company did not receive a salary for the year ended December 31, 1999.

During 1998, the Company entered into a collaboration agreement with Inpharmakon Corporation, an affiliate of an officer of the Company, under which Inpharmakon will assist the Company in developing their FHPC 01 product. This agreement was amended in May 2000 as discussed in Note 9. The Company paid \$1,000, \$201,000 and \$200,000 to Inpharmakon in 1999, 2000 and 2001, respectively.

On January 11, 1999, Kapoor-Pharma Investments, L.P., an affiliate of one of the directors of the Company, loaned the Company \$1.6 million at an interest rate of 2.0% over the prime rate of interest. In November 1999, the Company converted principal and \$145,000 of accrued interest totaling \$1.7 million into 837,593 shares of common stock at \$2.083 per share, pursuant to the terms of the loan agreement.

In connection with the bridge loan agreement discussed in Note 2, the Company paid a fee of \$17,000 to a trust affiliated with John N. Kapoor Ph.D., a director of the Company, in return for the pledge of certain Trust assets as collateral for the loan.

## FIRST HORIZON PHARMACEUTICAL CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

## 13. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table sets forth summary quarterly financial information for the years ended December 31, 2000 and 2001 (in thousands):

2000 BY QUARTER	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOURTH QUARTER
Net revenues.....	\$ 7,120	\$ 7,844	\$ 9,633	\$ 12,054
Gross profit.....	6,058	6,684	8,231	10,241
Operating income.....	8	454	1,479	2,180
Net (loss) income.....	(39)	177	955	1,414
Earnings per share:				
Basic.....	\$ --	\$ 0.01	\$ 0.05	\$ 0.07
Diluted.....	\$ --	\$ 0.01	\$ 0.04	\$ 0.06
2001 BY QUARTER	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOURTH QUARTER
Net revenues.....	\$ 12,453	\$ 12,979	\$ 18,510	\$ 25,348
Gross profit.....	10,682	11,272	15,681	21,301
Operating income.....	1,767	3,060	4,479	6,398
Net income.....	1,227	2,268	3,159	4,069
Earnings per share:				
Basic.....	\$ 0.06	\$ 0.09	\$ 0.12	\$ 0.15
Diluted.....	\$ 0.06	\$ 0.09	\$ 0.11	\$ 0.14

Quarterly amounts do not add to annual amounts due to the effect of rounding on a quarterly basis.

## 14. SUBSEQUENT EVENTS

On February 12, 2002, the Company entered into a definitive agreement to acquire certain U.S. rights relating to the product, Sular, from AstraZeneca UK Limited. The Company also entered into a long term manufacturing, supply and distribution agreement with Sular's current manufacturer, Bayer AG. The purchase price for the transaction is \$185.0 million, plus the assumption of certain liabilities. In addition, the Company will pay up to \$30.0 million in additional purchase price after closing, based on the achievement of certain performance milestones. The Company anticipates that it will complete the transaction in the first quarter of 2002, subject to the approval under the Hart-Scott-Rodino Antitrust Improvements Act and the satisfaction of certain other customary closing conditions.

In order to finance the acquisition, the Company received a commitment on January 31, 2002 for a six-month \$152.0 million senior secured credit facility arranged through Deutsche Banc Alex. Brown Inc. consisting of a \$127.0 million term loan and a \$25.0 million revolving loan. The Company expects to borrow \$127.0 million under the term loan and \$10.0 million under the revolving loan to partially fund the purchase of Sular. Borrowings under the term loan bear interest at the Company's option at the base rate in effect from time to time plus an applicable margin or the Eurodollar rate, plus an applicable margin, and mature six months from the closing date of the Sular transaction. Borrowings under the revolving loan bear interest at the Company's option at the base rate in effect from time to time plus an applicable margin or the Eurodollar rate, plus an applicable margin, and mature three years from the closing of the Sular transaction, provided that, in the event the term loan is not repaid in full from the proceeds of one or more stock offerings or other junior financing, on or prior to the term loan maturity date, then the revolving loan will mature on the same date as the term loan. In conjunction with this new facility, the Company's existing revolving loan facility discussed in Note 2 will be terminated.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders of  
First Horizon Pharmaceutical Corporation

We have audited in accordance with auditing standards generally accepted in the United States, the consolidated financial statements of First Horizon Pharmaceutical Corporation (a Delaware Corporation) and subsidiary included in this Annual Report and have issued our report thereon dated February 12, 2002. Our audit was made for the purpose of forming an opinion on the basic financial statements taken as a whole. The accompanying schedule of Valuation and Qualifying Accounts is the responsibility of the Company's management and is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

ARTHUR ANDERSEN LLP

Atlanta, Georgia  
February 12, 2002

## SCHEDULE II

## FIRST HORIZON PHARMACEUTICAL CORPORATION

VALUATION AND QUALIFYING ACCOUNTS  
YEARS ENDED DECEMBER 31, 1999, 2000 AND 2001  
(IN THOUSANDS)

CLASSIFICATION		BALANCE OF BEGINNING OF YEAR	CHARGED TO COSTS AND EXPENSES		BALANCE END OF YEAR
			DEDUCTIONS		
1999	Allowance for doubtful accounts and discounts.....	\$ 36	\$ 51	\$ (31)	\$ 56
	Allowance for product returns.....	140	367	(235)	272
	Allowance for sales deductions.....	--	1,294	(443)	851
2000	Allowance for doubtful accounts and discounts.....	56	375	(147)	284
	Allowance for product returns.....	272	737	(184)	825
	Allowance for sales deductions.....	851	4,015	(3,052)	1,814
2001	Allowance for doubtful accounts and discounts.....	284	1,064	(261)	1,087
	Allowance for product returns.....	825	3,167	(618)	3,374
	Allowance for sales deductions.....	1,814	10,174	(6,351)	5,637

EXHIBIT 21

SUBSIDIARY OF THE REGISTRANT

First Horizon Services, LLC

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EXHIBIT 23

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our reports included in this Form 10-K, into the Company's previously filed Registration Statement File No. 333-40856 and File No. 333-39106.

ARTHUR ANDERSEN LLP

Atlanta, Georgia  
March 27, 2002

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